U.S. FOOD AND DRUG ADMINISTRATION

New Humanitarian Device Approval

FDA approved this device under the Humanitarian Device Exemption (HDE) program http://www.fda.gov/cdrh/ode/hdeinfo.html. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: AbioCor® Implantable Replacement Heart
Manufacturer: Abiomed, Inc.
Address: 22 Cherry Hill Drive, Danvers, MA 09123
Approval Date: September 5, 2006
Approval Letter: A link to web for the approval letter

What is it?

The AbioCor is an electrically powered pump (pulsatile electrohydraulic device) used to replace the main pumping chambers (the ventricles) of the human heart. It can deliver up to 8 liters of blood per minute over a broad range of blood pressures. The device consists of a "Thoracic Unit" containing two sealed blood pumps, separated by an energy converter. The Thoracic Unit is connected to the heart's two upper collecting chambers (the atria) and the two major outgoing vessels supplying blood to the lungs and to the rest of the body. (The heart's lower pumping chambers, the ventricles, have been removed). The energy converter moves hydraulic fluid from one side of the device to the other, squeezing a sac containing the blood in one side of the pump to force the blood through the connected outgoing vessel. Simultaneously, blood is actively drawn into the pump on the opposite side, filling it for the next cycle .which will discharge blood to the other outgoing vessel.

How does it work?

The AbioCor is designed to duplicate the function of the normal heart by circulating blood through the body and the lungs. An implanted *controller* regulates and monitors the Thoracic Unit. The *controller* can receive and transmit information by way of radio communication to a system that is external (not connected) to the body, There is also an implanted battery that can operate the implanted system in the absence of the external power source, thereby allowing the patient to be free from all external connections.

A coil implanted under the skin can receive energy (by induction) from an external power source to recharge the implanted battery. An external controlling device allows one to monitor the status of the implantable system and also can alter the system's operating conditions.

When is it used?

The AbioCor is indicated for use in patients who;

- have both major pumping heart chambers (the ventricles) that are failing
- have end-stage heart disease
- are not transplant candidates
- are less than 75 years old
- are not treatable by single left ventricular heart assist devices for destination therapy
- are not able to be withdrawn from heart support measures

What will it accomplish?

The AbioCor may provide circulatory support to patients with severe heart failure. Moreover, the device may have the ability to restore normal flow of blood and blood pressures and restore organ function (e.g. kidneys and liver) in patients who are not heart transplant candidates.

When should it not be used?

The AbioCor should not be used in patients who are eligible for a heart transplant, in patients where the device will not fit, in patients who cannot be successfully treated for blood clotting disorders or who have only left sided heart failure.

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Concurrence:
HDE Number: H040006

N.B. The 'Prepared by,' ' HDE Number,' and 'Concurrence' information will be deleted before posting to the CDRH Internet.
Rev. 04/03/01

Patient Labeling

AbioCor™

Implantable Replacement Heart System

PATIENT AND FAMILY GUIDE

&

FREQUENTLY ASKED QUESTIONS

Statement concerning FDA Approval

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Contents

Introduction

This Patient and Family Guide ("Guide") is intended to address questions and concerns of patients who are candidates for the AbioCor™ Implantable Replacement Heart System (AbioCor) and their families. It is intended to aid you in answering questions you may have about what it means to have an AbioCor.

This Guide does not cover details of the AbioCor clinical trial, but does provide information on serious events, such as strokes. Detailed data and pertinent information from the clinical trial can be found in other documents including the Summary of Safety and Probably Benefit published by the FDA, Instructions for Use provided by ABIOMED and the Informed Consent the Hospital would ask you to sign.

There are serious risks associated with the AbioCor device; however, there is also the potential for extending life. These risks and benefits will be discussed in more detail in the Guide and with your health care team.

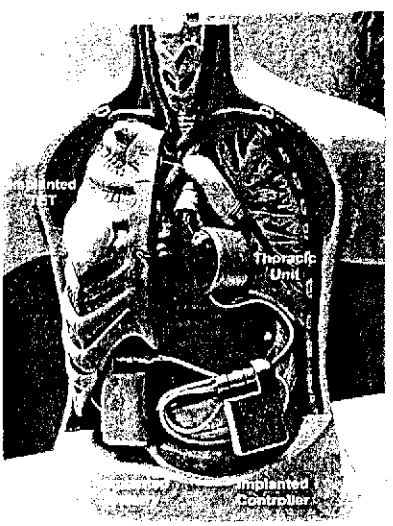
This Guide is one part of the information available to you. Your physicians, nurses, surgeons and hospital administrators can answer other questions.

Overview of the AbioCor

You have been given this Guide as a reference to better understand the Abiocor device and how its use can affect your health. If you are interested in learning more, your physician can contact ABIOMED, the manufacturer of the AbioCor for information, or the nearest qualified AbioCor Medical Center.

What is the AbioCor?

The AbioCor is a mechanical device that replaces the pumping function of your heart in which your own native heart will be removed from your body. The AbioCor is surgically implanted into your chest along with other components necessary for proper function. It is designed to fit within your body, in the space where your native heart resided. Because parts do not cross the skin, you can remain mobile and potentially live a near normal life. This feature minimizes the risk of infection that might have otherwise occurred if AbioCor components crossed the skin barrier. External power source is part of the system but power delivery is achieved across the intact skin.



The AbioCor system consists of the following implanted components:

- Thoracic Unit (the pump)

The thoracic unit, weighing approximately two pounds, includes two artificial ventricles (blood pumping chambers). It takes over the pumping function of the diseased heart, which is removed during the implantation procedure.

- Power Transfer Coil (the power supply)

This component (or "TET") powers the system across the skin and recharges the internal battery from the outside.

- Implanted Controller (the mechanical programmer)

- Implanted Battery (short-term power)

The controller and battery are implanted in the abdominal region of your body. The controller monitors and controls system operations, including the pumping rate of the heart. The battery allows the recipient to be free from all external connections for a short period of time, generally up to one hour.

In addition, there are external components to adjust the device and provide safety monitoring. A portable external power supply and hand-held monitor make the system simple to use during routine activities once you are discharged.

What Patients might potentially benefit from the AbioCor?

The AbioCor is intended for patients with complete heart failure. Heart failure is a condition in which the heart muscle has weakened to the point that it has difficulty pumping the required minimum amount of blood to the rest of the body. Heart failure generally develops over time from many causes such as injury to the heart muscle resulting from heart attacks, untreated high blood pressure putting excess load on the heart, and/or leaky heart valves making the heart work harder but not efficiently. These conditions alone or together weaken the heart muscle over time so it is not able to deliver the required amount of blood.

If you and your doctor at a qualified AbioCor center agree

that the AbioCor may be the appropriate treatment for you, a thorough medical evaluation will be performed. Your past medical history and any related medical information will be obtained with your consent. Additionally, you will have a Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scan to determine if the pump will fit in your chest.

What should I expect if I wish to go forward?

If it is determined that you could potentially benefit from the AbioCor, your physicians will discuss with you and your family additional information regarding the risks and benefits of the procedure through an Informed Consent process. More details of the actual risks and benefits from the initial clinical trial will be provided to you at that time.

During the consent process, a Patient Advocate will be available to help you understand the information in the consent form and answer your questions. The Patient Advocate maintains a role of "neutrality" and is there for your benefit only. The Patient Advocate will also discuss with you end-of-life care options should you decide not to proceed and if you do decide to proceed, what decisions may be necessary if at some point the device is discontinued.

Is the AbioCor Approved by the FDA?

Yes, the Food and Drug Administration (FDA) has approved the AbioCor for use under a Humanitarian Device Exemption (HDE). Its use is limited to a specific category of patients with end-stage heart failure on both sides of the heart who have no other treatment options. An HDE designation means that FDA has found the device to be safe and provide probable benefit to your health. The AbioCor was in clinical testing in 14 patients in a trial before FDA approved it under the HDE.

In compliance with the HDE, the FDA requires that there be a Post-Approval Study performed to monitor the use and outcomes of the AbioCor while it is being marketed in the United States. This is to ensure that results in actual clinical use are at least similar to those observed in the clinical trial. For the AbioCor, this Post-Approval Study will consist of at

least 25 subjects in no more than 10 US heart centers.

General Questions

Who is a candidate for an AbioCor?

Candidates for the AbioCor are patients with complete heart failure, who are not eligible for a heart transplant or other mechanical device at the time of evaluation for an AbioCor and who are in imminent threat of death. Selected candidates will also need to meet various medical criteria, have a support system in place to assist them in recovery, and physically be a "size" match for the device.

AbioCor patients are not candidates for heart transplantation. Heart transplantation is usually offered to someone who has end-stage heart failure, but whose death is not imminent and whose overall medical condition is likely to withstand aggressive immunosuppression following transplant.

What are the potential benefits of the AbioCor?

The potential benefits of the AbioCor are specific to each individual. For some patients, knowing that there is some form of treatment possible when transplantation is not an option is of benefit. Some patients will be able to go home and have a respectable quality of life with their loved ones. For others, their clinical status will make for an extended and difficult recovery. From the initial clinical trial, we know that each patient's recovery is different and that each patient chose to go forward with the AbioCor for different reasons, some for the additional time with family and friends despite a recovery course that could confine them in the hospital during which the patient may suffer a neurological event (for example, a stroke) or suffer a bleeding event..

Although results will vary, some of the following benefits are possible:

1. **Increase in life expectancy.** Patients who receive the AbioCor are in imminent threat of death. They are in advanced heart failure. The AbioCor may prolong your life, however, it is difficult to know for how long compared to what would have happened without the device.

2. **Lower risk of infection.** Because the device is totally implantable, there may be a lower risk of infection compared to other devices that penetrate the surface of the skin.

3. **Improved quality of life.** Your quality of life during the time you are supported by the AbioCor Implantable Replacement Heart may be better than the quality of life you would enjoy were you to receive conventional medical therapy. Your quality of life could also be worse than what you are experiencing now.

4. **Extended time with family and friends.** The AbioCor, by extending life, may provide you with valuable time with family and friends. Some patients see this additional time as time to "put affairs in order."

5. **Patient autonomy.** Patients may find benefit in knowing that they have some decision-making ability or some control over their final treatment choices. You may find some satisfaction in having your decision honored and by knowing that all treatment options have been explored.

What are the risks involved in the AbioCor?

As with any major surgery, there are risks. From the initial clinical trial, some of the risks have been identified and are described below. In addition, because of the severity of your illness, your risks may be higher than others who undergo open heart surgery.

1. **Death:** There is a risk of dying during surgery and at any point afterwards when you have the device implanted. You should discuss your risk of dying during surgery with your physicians.

2. **Bleeding:** There may be unusual and excessive bleeding from both surgery and clotting disorders. There may also be bleeding issues after the device has been implanted.

3. **Stroke:** Strokes are usually caused from blood clots become lodged in small vessels and restrict blood flow and vital nutrients to the surrounding area. Anticoagulation (blood thinners) will be used to minimize the risk of clotting. Additional information on strokes is provided in this Guide.

4. **Infections:** Localized infections might occur as well as infections that could spread through your body. These include infections of the blood stream (bacteremia or septicemia), infection of the chest cavity (mediastinitis), lung infections (pneumonia or lung abscess), and "pocket" infection or abscess in the area of the implanted AbioCor controller or battery pack.

5. **Kidney failure:** Partial or total loss of kidney function may occur. Short-term loss can be corrected with temporary dialysis. Chronic renal failure may require permanent dialysis. You most likely would not qualify for a kidney transplant.

6. **Liver failure:** You may have a poorly functioning liver to begin with. Your liver function may become worse off or not improve at all. This will compromise your recovery. You most likely would not qualify for a liver transplant.

7. **Abdominal discomfort:** The implantable components may cause discomfort in the abdominal muscles, especially when bending over. You may feel "full" earlier than usual after eating and this may affect your appetite.

8. **Anemia (decreased red blood cells):** Some patients become anemic. Anemia makes you feel tired or short of breath.

9. **Injury to soft tissues:** The implantable components may create enough heat to cause pain, soreness or injury to surrounding tissues. Device run condition may need to be adjusted to alleviate such a condition.

10. **Esophagus obstruction:** The device may push upon the esophagus (tube connecting the mouth and the stomach) and this could interfere with your appetite. It may cause discomfort, cramps, or slow the movement of food through your body. It could also prevent you from eating.

11. **Device failures:** Like any other man-made device, the AbioCor is subject to mechanical failure. Your physicians and the team at ABIOMED work diligently to prevent system failures and will closely monitor the device at all times.

12. **Inability to close the chest:** Every effort will be made ahead of time to see that the AbioCor will fit into your body. Despite these efforts, it might be impossible to bring your breastbone back together after surgery. If this happens, the surgeon may take special steps to allow your chest cavity to be closed and complete the surgery.

13. **Impaired breathing:** The nerves that enable the diaphragm muscle to move air into your lungs could be injured during the surgery. If this happens, your breathing may be supported artificially for a temporary period of time on a respirator.

14. **Repeat surgeries to replace parts:** Some components of the AbioCor need replacement periodically. For example, the implanted battery is expected to last approximately one year. This would necessitate repeat surgery and would require your consent. You should not expect the AbioCor to last indefinitely.

15. **Attention to charging batteries and obeying warnings:** The Abiocor operates by rechargeable batteries. There is a battery on the inside of your body and a battery on the outside of your body and they must not become completely discharged. The AbioCor automatically provides messages and warnings about the amount of energy remaining in the batteries. These messages will require your immediate attention.

16. **Restrictions on lifestyle and employment:** Although the AbioCor is designed to enable you to perform routine daily activities including light work, it is unlikely that you will be

able to return to the lifestyle you experienced before becoming ill, including regular employment. While bathing and shallow swimming are permissible, you cannot submerge your body under water. You will have limitations on traveling.

17. **AbioCor pump replacement:** If necessary, the AbioCor pump may be replaced; however, it cannot be determined beforehand whether this is possible. Due to the presence of scar tissue and other complicating factors you may be unable to receive a replacement AbioCor pump even if you needed one. In such a case, your life expectancy will be limited by the durability of the AbioCor.

How does the heart rate adjust to changes in activity?

The natural heart responds to changes in the body's need for oxygen and blood by increasing and decreasing the heart rate and volume of blood pumped to the body. This response is partially controlled by the sympathetic and parasympathetic systems (the so-called "fight or flight" mechanisms) and baroreceptors (pressure sensors in some of our vessels).

Some of these natural responses no longer work with the AbioCor. However, you can change your heart rate as needed using the external electronic control.

Will my own heart be completely removed?

Almost totally. Your heart consists of four chambers, the lower two (ventricles) will be completely removed. The upper two chambers (atria) will be partially removed and the remaining tissue will be used to anchor the AbioCor. Once removed, your heart tissue can not be reconstructed.

Will I feel any pain once the AbioCor is in place and functioning?

The surgery is extensive and you should expect to have pain and discomfort following surgery. This will be monitored and managed with pain medication to make you as comfortable as possible. Pain sensation and tolerance are variable among patients and your physicians will work hard to see

that it is controlled through medication during and after surgery.

Evaluation for the AbioCor

How will I decide if the AbioCor is right for me?

Your physician and other members of the health care team will help you make the decision as to whether the AbioCor is right for you. You will be assigned a coordinator who will collect information, schedule appointments and keep you informed of the process.

A medical evaluation will enable your health care team to determine whether the AbioCor is a viable option. This evaluation requires several tests over a few days and may include the following:

1. Physical Examination and Cardiac Diagnostic Tests

Your physicians and surgeons will perform a thorough physical examination, review your past medical records and order one or more of the following tests:

- **Echocardiogram** – ultrasound images of your heart; views chambers and heart pumping function
- **Electrocardiogram (EKG or ECG)** – a reading of your heart's electrical activity; measures rhythm and regularity of your heartbeat.
- **Left Ventricular Performance Study (LVPS)** - a non-surgical test that measures the pumping capability of the left ventricle of your heart.
- **Cardiac Catheterization** – detects blocked vessels, valve disorders and other potential problems.
- **Swan Ganz** – a catheterization technique that measures the blood flow that your heart produces and pressures that are important for a full assessment of your heart condition.
- **Computed Tomography (CT) or Magnetic Resonance Imaging (MRI)** - noninvasive procedures that provide images of your internal organs, allowing

your doctors to assess whether the AbioCor will fit into your chest.

2. Medical History

Your health care team will review your past medical history. Besides heart failure cardiologists and heart surgeons, other specialists in clotting disorders, neurology, respiratory problems, liver and kidney function will also be involved in the initial evaluation.

3. Nutritional Assessment

A nutritionist will evaluate your dietary habits and make recommendations for a diet to optimize your recovery. This plan will require measurements of your weight, body fat and muscle mass. A recommended diet will be established to help you prepare for the best surgical outcome and proper healing after surgery.

4. Social Services Evaluation

A clinical social worker will meet with you and your family during your initial evaluation to gather information about your experiences since your illness began, including its effects on your lifestyle, personal relationships, job, and financial status. The evaluation will also take into consideration what special needs you may have once discharged, for example, ease of access into your home, electrical needs and transportation needs.

5. Patient Advocate Assistance

A Patient Advocate will be available to you to discuss treatment options, end-of-life care and the informed consent process. The Patient Advocate may have experience in hospice care and other end-of-life issues and can assist you in better understanding the total impact of living with the AbioCor or what options would be available to you should you decide not to proceed.

What is end-stage heart disease?

End-stage heart disease is a heart condition of any origin that has progressed to a life-threatening or terminal ("end")

stage such as yours. Patients in heart failure usually have had a history of severe progressive deterioration, multiple heart attacks, and surgical and/or medical interventions. The condition may progress over many years, however, eventually, the disease becomes life threatening when all conventional medical and surgical treatments are no longer effective and, a person with such condition will die unless their heart's function is artificially restored.

Before and during Surgery

What should I expect preparing for surgery?

It is natural to be apprehensive about surgery. You may wish to spend time with your family, friends, religious leader and other important individuals for a few days before surgery discussing with them what you feel is important for them to know about your plans and wishes. Knowing what to expect will ease your anxiety and aid in your recovery. Each person, procedure, device and machine plays a special role in your recovery. The following information explains what will happen as you prepare for surgery.

The Evening and Morning Before Surgery

You will not be able to eat or drink after midnight the night before surgery unless your physician instructs you differently. You will be given an enema to aid in emptying your bowel. An IV will be inserted into your arm and an antibiotic will be administered.

Transfer to the Operating Room

Immediately prior to surgery, your family will be escorted to a waiting area and you will be transported to a "holding area." You will feel drowsy from a general sedative. You can expect the temperature in this room to be cool. A nurse will be there to make sure that everything is ready and will help you if you need anything.

What will be done to me in the operating room?

Once inside the operating room, nurses will assist you in moving to the operating table. You will remain conscious until further drapes and equipment are in place. A large IV will be placed in the side of your neck which may cause a slight sting or feeling of pressure. Once in place, it will be used to administer fluids and medications. You will undergo general anesthesia for the duration of the operation. Areas of your body for exposure during surgery will be shaved and swabbed with sterile solution. A tube will be inserted into your airway to help you breath. Bladder drainage will be

achieved through a catheter (small tube) placed in your urinary canal. Blood tubings will be place in your veins and arteries to help circulate oxygenated blood through your body when your heart is being removed and the AbioCor put in.

Immediately following surgery

Where will I be when I wake up?

It may be several hours, possibly days, before you completely wake up from surgery. At this time, you will be in the Surgical Intensive Care Unit (SICU). You will not be allowed to completely wake up until the breathing tube has been removed and you can breathe without mechanical assistance. You may, however, have an oxygen mask in place when you wake up to make breathing easier. The room will be full of monitors, equipment and at times, many hospital personnel. Your family will be able to visit you in the SICU, but it will be limited.

What can I expect during my immediate recovery?

Depending upon the complexity of the operation, and your health before surgery, you could be hospitalized for weeks or months following surgery. Every patient will differ in their recovery process. With appropriate rehabilitation, you might be back to non-strenuous activities within a few weeks.

As you continue to improve, less mechanical support will be necessary. You may be fed through a nasogastric ("feeding" tube) that goes into your nose and down the back of your throat. You may need extra oxygen through a mask or prongs that sit at the openings of your nose. You will have a catheter in your bladder for urine collection and it may create a pressure sensation.

As you begin to move around in bed, you will feel your surgical incisions. These maybe painful at first, especially when you are asked to cough, turn in bed, or move. You should tell your nurse when you are having pain. Initially, you will have chest tubes in place that run from under your ribs to containers hooked to the bedside. These tubes collect fluid in the chest that may build up after surgery.

What else will aid in my immediate recovery?

As you continue to improve, you will need less support and you will be moved from the SICU to a cardiac care unit. It is likely you will still have several IVs, possibly oxygen and some nutritional support when you are moved. Your mobility will be limited, however, physical therapy will be working with you to improve your range of motion. It is reasonable to expect periods of pain, discomfort, even depression and isolation. As you begin to take a more active role in your recovery, you will notice that your surgical incisions are sore and there may be itching and/or numbness at the incision site. You may also see some bruising and/or redness around the area. This is part of the normal healing process and will disappear with time.

At all times, your health care team will be assisting you and your family through this period of adjustment. There will be times of despair and confusion, however, everything possible will be done to aid in your recovery and assist in making you comfortable as you heal. It is normal to expect some days to feel better than others.

Who will operate the AbioCor Console?

While you are in the hospital, an AbioCor-trained nurse will operate the AbioCor console. In time, you or a caregiver may assume that role and learn to operate the console.

Recovery

What emotions am I likely to experience as I recover?

It is normal to experience a range of emotions, from relief to despair. Few patients have had a similar experience and each of them handles the emotional and psychological impact of receiving the AbioCor differently. You should take advantage of every opportunity to discuss your feelings with a caregiver, family member or friend. Some patients find keeping a journal of their experience a helpful way to express themselves.

What should I know about the risk of having a stroke?

A major concern associated with the AbioCor is the risk of stroke. In the clinical trial, the majority of the patients did experience a stroke. Your physician will discuss with you your individual risk, however, some of the common concerns are addressed here.

Stroke is a cardiovascular disease that affects the blood flow to the brain. A stroke occurs when a blood vessel bringing oxygen and nutrients to the brain is clogged by a blood clot or some other particle, or ruptures and bleeds. Because of this rupture or blockage, part of the brain doesn't get the blood flow it needs and brain tissue is damaged or permanently destroyed. This area of the brain can cease to function properly. The effects of stroke are often permanent because dead brain cells generally do not undergo replacement during adult life.

Are there different kinds of strokes?

Yes. Cerebral thrombosis is the most common type of stroke. It occurs when a blood clot ("thrombus") forms and blocks blood flow in an artery bringing blood to part of the brain. Blood clots can form in arteries damaged by atherosclerosis ("hardening of the arteries"). Blood clots could also form in the AbioCor pump, or in the places where the AbioCor is connected to the remaining heart tissue. A

blood clot that causes a stroke can be due to the pre-existing atherosclerotic disease or to the AbioCor.

A second type of stroke is a hemorrhagic (bleeding) stroke. This type of stroke may result from abnormal blood coagulation caused from natural causes, such as liver failure, or leaky vessels. It can also be caused from an imbalance in anticoagulation therapy required with the AbioCor. The excess bleeding in the brain increases the pressure in the surrounding tissue and ultimately can stop blood flow to the affect area. As with thrombosis, this can lead to permanent or partial brain damage. The chance of recovery is totally dependent on the severity of the event.

What capabilities are affected by a stroke?

Stroke affects different people in different ways, depending on the type of stroke, the area of the brain affected, and the extent of the brain injury. Brain injury from a stroke can affect the senses, the ability to move, speech patterns and the ability to understand speech, behavioral patterns, thought patterns, memory, and emotions. Paralysis or weakness on one side of the body is common. The paralysis or weakness can range from mild and partial, to severe. Recovery can range from nearly complete, to partial, to none at all. Patients with bleeding complications are less likely to tolerate blood thinners and therefore more likely to experience strokes.

What about rehabilitation programs, in case I do suffer a stroke?

Rehabilitation is a very important part of recovery for many stroke survivors. The effects of stroke may mean that you must change, relearn, or redefine how you live.

Rehabilitation may include:

- Self-care skills such as feeding, grooming, bathing, and dressing
- Functional skills such as grasping, walking, or self-propelling a wheelchair
- Communication skills in speech and language
- Cognitive skills such as memory or problem-solving

- Social skills for interacting with other people

Will my taste for foods change?

It is not possible to predict whether your taste will change or, if so, how long it will be before it returns to normal, or whether it will return to normal. Some patients after heart surgery do experience a change in taste. Maintaining a good nutritional status will be vitally important to your overall recovery following surgery. Therefore, if you find that your taste changes or your appetite is not as it was before surgery, take caution to keep finding foods that appeal to you so that your nutritional input will sustained. You can always consult with the nutritionists who may have suggestions for seasoning your food or preparing it in different ways to improve the taste.

Will I be able to shower or take a bath?

Yes, however, do not bathe, shower, or get your incisions wet until they are fully healed, usually 10 to 14 days after surgery or until recommended by your physician. If you have adhesive strips on your incisions, you can remove them when they appear ready to peel from the skin.

When you bathe or shower with the AbioCor, you will take off the skin transformer (TET) coil and rely on the stored energy in the rechargeable battery in your abdomen to supply power to the AbioCor. This temporary assistance is good for approximately one hour. When you get out of the bath or shower, you should reposition the TET on your chest.

When you bathe or shower, you should observe the following:

- Always be sure to check that the implanted AbioCor battery in your abdomen is fully charged before you take a shower.
- Shower rather than bathe for at least the first 3 weeks following surgery.

- Avoid extremely hot or cold water—this can interfere with normal circulation or medications.
- If you prefer to shower and have been told to sit while showering, use a well-secured stool in the shower.
- Gently wash your incisions with warm, soapy; don't scrub. Pat incisions dry with a towel but do not vigorously rub them.
- If taking a bath, steady yourself before standing. You may feel weak or light-headed. Always have someone nearby for assistance.
- Use a long-handled brush for washing your back and lower legs.
- Place a chair near the shower or tub to use while you are drying and dressing. You may find it easier to dress while sitting.

Will I notice the device when I try to sleep?

It is recommended that you use the AbioCor Console to provide power to the AbioCor while you sleep (rather than the PCE and battery packs). The external TET will need to be in place on your skin while you sleep. You need not worry about its positioning as long as you use the Velcro straps, taped to your skin, that hold the TET in place. To avoid tangling the TET cable, it may be necessary to tape or clip the cable to the bottom sheet, along the length of your body.

Will I have swelling?

Yes, you may experience swelling in your legs and other extremities. There are many reasons this may occur and most can be corrected. If this persists, please notify your physician.

Will I need to take immunosuppression drugs?

No. The AbioCor is made of plastics and titanium metal that are compatible with body tissues. Unlike patients who receive a human heart transplant, you will not need to take immunosuppressive drugs to prevent rejection.

Discharge and Continued Recovery

When will I be able to go home?

You are ready for discharge when your wounds from surgery have healed, your diet and medication intake are stable, you have regained strength, be able to manage self care and have been trained on the AbioCor. In the initial trial, one patient was discharged to a hotel near the hospital. Another patient was discharged home. Two others left the hospital on day excursions, but the remaining 10 patients did not leave the hospital.

Your discharge and return to home will occur in "stages" including first outings away from the hospital for a couple of hours, followed by over night stays at hotels near the hospital, and finally home. If you need rehabilitative care, you may go to a step-down facility for some time prior to going home. Prior to discharge, your physician and nurse will be reviewing your medications and chart. You will be given instructions about medications, activity, and diet for when you are discharged.

When qualified for discharge, patients are mostly capable of taking care of their personal needs at home. However, you will need someone to help you get to the grocery store and other places for errands or social activities. If you live alone, please notify the nurse coordinator, who will arrange for you to speak with the social service worker regarding any needed help at home.

How will the patient-carried electronics (PCE) affect my activities?

The AbioCor PCE unit and external battery packs are the primary source of power for the device when you are away from the main console. The PCE is the size of a brief case and can be pulled in a rolling cart or carried over your shoulder. The PCE is suitable for non-strenuous mobile activities or strenuous stationery activities, such as cycling on a stationery bike.

What about driving a car?

Immediately after you are discharged from the hospital you can ride, but not drive a car. Always wear the shoulder strap and safety belt while riding. Driving may be allowed once you have fully recovered and able to resume other routine activities without assistance. None of the AbioCor patients drove a car after receiving the device.

What about medications after I am discharged from the hospital?

Prior to discharge, your physician will review your medications with you and your caregivers. You will be on blood thinner and other anticoagulation medicines as long as you have the AbioCor. You will also receive prescriptions for pain medication and sleeping pills. It is very important that you follow the medication regimen prescribed by your physician. Failure to follow instructions may increase your risk for strokes and other complications. In taking prescription medications, follow these important rules:

- Keep a record of each medication, its purpose, and dosage. Take only as prescribed.
- Take pain relief medication on a regular basis, especially if you have activities planned.
- Check with your physician before taking any over-the-counter medication, as it may interfere with your prescribed medications.
- Tell your physician if you develop a reaction to your medication, such as skin rash, fever, vomiting, diarrhea, jaundice (yellow eyes and skin) or severe bruising.
- Carry an up-to-date wallet-size record of all medications you are taking and their dosage.
- Carry a card (which includes your physician's contact information) indicating that you are an AbioCor Implantable Replacement Heart recipient.

What about physical activities after I am discharged?

It is important to gradually increase your physical activity level. Your cardiac rehab team will recommend a daily goal for of exercise. You should do it as directed for a week, then evaluate how you are tolerating that level of exercise. If you feel you can do more, increase your activity a little for the next week. Doing this week by week, you will gradually increase the amount of exercise you can do and give your body time to recover.

Will I be able to lift things?

It generally takes the sterum ("breastbone) about 8 weeks to heal following surgery. Until this time, lifting and physical activity should be limited. Avoid activities that cause you to strain or bear down, such as lifting children onto your lap or lifting things over your head. You should NOT lift anything or anyone heavier than 10 pounds for at least 8 weeks following surgery. Also, do not strain yourself attempting to open stuck windows, unscrew tight jar lids, push open heavy doors or move furniture. Shopping bags, suitcases, large purses, briefcases, large pets and children almost always weigh more than expected.

What will I be able to eat?

Good nutrition will play a vital role in your recovery. Your appetite may take some time to return to normal. Therefore, you will have to consciously monitor your eating habits and optimize your food intake to get a healthy, balanced diet. Medications are available to help if your appetite remains low. You may not be able to eat normally if the device is compressing your esophagus (swallowing tube).

The American Heart Association recommends that people carefully monitor the amount of fatty foods consumed, especially those high in saturated fats. You will have the most success in changing your diet if you gradually discontinue the unhealthy foods and substitute those low in cholesterol and fat. In general, you should consume fewer than 25% of your calories as fat and eat five servings of vegetables or fruit a day.

What about recordkeeping?

You will be required to keep some information and data on an ongoing basis to ensure that the AbioCor is functioning properly. This will include your; (1) temperature, (2) AbioCor beat rate, (3) blood pressures, (4) weight each morning and (5) medications taken

How much rest will I need after I am discharged?

Try to get 8 to 10 hours of sleep per night. You should alternate exercise and other activities with periods of rest.

What about sex?

It is normal to be apprehensive about sexual activities. Make sure to communicate with your partner your concerns and resume intimacy slowly, hugging, kissing and touching.

You should be able to engage in sexual intercourse when you are able to walk 4 blocks at a moderate pace or climb 2 flights of stairs without shortness of breath or significant fatigue. Your sternum should be completely healed.

Pregnancy Caution! Women with the AbioCor should avoid becoming pregnant.

What about smoking?

If you smoke, take steps to quit immediately. Smoking is a proven risk factor for cardiovascular disease.

Will I still feel short of breath?

The AbioCor can provide enough blood flow to deliver oxygen and nutrients to your tissues, sufficient for many routine activities. However, it is possible that you may feel short of breath if your activity requires blood flow greater than the maximum the AbioCor can provide. There are many reasons you can become short of breath; if you are concerned, you should contact your physician immediately.

What other sensations might I have?

Heart beats. The AbioCor is made of plastic and titanium and you may feel a different heart beat than what you normally experienced. You may hear a low level whirling and clicking sound from the AbioCor pump.

.**Dizziness**. You should not be dizzy if you move slowly from lying down, to sitting, and then to standing. If dizziness occurs at other times, contact your physician.

Blacking out. "Blacking out" or fainting indicates a possible problem and you should notify your nurse or physician as soon as possible.

Mood swings. You may feel anxious or depressed. Your health care team will include a social worker and psychologist to help you and your family. They can offer guidance for treating depression and advice on anti-depressants.

Chest pain. Most chest pain is from your surgical incisions and decreases over time. If you have new chest pain or increasing chest pain, call the nurse or physician.

Pain. It is normal to experience various levels of pain while you recover. Medications can help you feel better. It is important to take the pain relief medication early, and to ask for enough pain relief medicine to be able to move as comfortably as possible.

Would I know if something is wrong with the AbioCor?

The AbioCor is a machine and is affected by the normal "wear and tear" of operating continuously. Problems with its operation may cause you to feel similar to how you felt when your own heart was failing – short of breath, sluggish, puffy, and dizzy. In many instances, there are audible and visible messages or alarms that may appear on the AbioCor Console, to alert caregivers to abnormal conditions or impending failures. You and your caregivers should become familiar with the sounds generated by the AbioCor using a stethoscope. Changes in the sounds can be a hint to potential problems with the device and you should contact your hospital caregiver.

The AbioCor Console monitors the system's performance continuously and the information relayed is reviewed by care monitors at your care center and ABIOMED. Changes can be made through the console immediately if necessary.

How will I learn how to operate the AbioCor?

You will learn how to operate the AbioCor from what training manuals, one-on-one training with AbioCor-trained nurses, and hands on practice with the AbioCor equipment. You will receive as much training as you need to feel comfortable and confident to operate the AbioCor under normal circumstances. You will be tested periodically to demonstrate your understanding of the device and its operation. If you are unable to operate the AbioCor, your caregiver(s) will be trained to do so

What kinds of responsibilities will my primary caregiver have?

Initially, when you are discharged from the hospital to a secondary facility, you will have 24-hour nursing coverage available to assist you and your primary caregiver. Once it is determined that 24-hour nursing coverage is no longer needed, it is recommended that you continue to have a caregiver with you at all times, even once you are home. Your primary caregiver may be a spouse, family member, or a friend. It is someone who is available to assist you following discharge and who is able to learn to operate and troubleshoot the AbioCor.

What is the average life expectancy after AbioCor surgery?

Your life expectancy with the AbioCor will depend on many things, including your age, how your body responded to surgery, your health status going into surgery and your initial recovery period. Some patients will not make it out of surgery. Some patients will not recover well enough to leave the hospital. Your care team will do their utmost to give you a chance to go home. While there is the possibility of extended life with the AbioCor, there should be no expectation that the current version of the AbioCor will function beyond one or two years. The longest survivor in

the initial AbioCor trial lived for around 17 months. The average survival time of the trial patients was 4.5 months.

Glossary

The Glossary includes a collection of terms that you may hear physicians and nurses use while you are in the hospital and can be your quick reference guide for you. It is not intended to be comprehensive, but may be helpful to you.

Abdomen - The area of the body between the bottom of the ribs and the top of the thighs.

Abdominal aorta - The portion of the aorta in the abdomen.

Aneurysm - A sac-like protrusion from a blood vessel or the heart, resulting from a weakening of the vessel wall muscle.

Angina or angina pectoris - Chest pain that occurs when diseased blood vessels restrict blood flow to the heart.

Angiography - An x-ray technique that makes use of a dye injected into the coronary arteries to study blood circulation through the vessels. The test allows physicians to measure the degrees of obstruction to blood flow. Circulation through an artery is not seriously reduced until the inside diameter of the vessel is more than 75% obstructed.

Anticoagulant - A drug that keeps blood from clotting; a blood thinner.

Antihypertensive - Any drug or other therapy that lowers blood pressure.

Aorta - The largest artery in the body and the initial blood-supply vessel from the heart.

Aphasia - The inability to speak, write or understand spoken or written language because of brain injury or disease.

Artery - A vessel that carries oxygen-rich blood to the body.

Ascending aorta - The first portion of the aorta, emerging from the heart's left ventricle and is connected to the AbioCor aortic graft.

Atherosclerosis - A disease process that leads to the accumulation of a waxy and/or a hard substance, called plaque, inside blood vessels.

Atria - The two upper or holding chambers of the heart.

Atrium - Either one of the heart's two upper chambers.

Autoregulation - When blood flow to an organ remains the same although pressure changes in the artery that delivers blood to that organ may have changed.

Bacteria - Germs that can lead to disease.

Balloon catheter - A long tube-like device with a small balloon on the end that can be threaded through a blood vessel. Used in treatment or in monitoring blood pressures and flow.

Baroreceptors - Pressure-sensitive areas in the aorta and carotid arteries that protect circulation during short-term changes in blood pressure and changes in body position (for example, lying down and standing up) by sending signals to the heart and brain that affect the body's response to blood pressure changes.

Beta blocker - An antihypertensive drug that limits the activity of epinephrine, a hormone that increases blood pressure.

Blood clot - A jelly-like mass of blood tissue formed by clotting factors in the blood. Clots stop the flow of blood from an injury; they can also form inside an artery whose walls are damaged by atherosclerotic build-up and can cause a stroke.

Blood pressure - The force exerted by the heart in pumping blood results in the pressure of blood in the arteries.

Bradycardia - Abnormally slow heartbeat.

Calcium channel blocker (or calcium blocker) - A drug that lowers blood pressure by regulating calcium-related electrical activity in the heart.

Capillaries - Microscopically small blood vessels between arteries and veins that distribute oxygenated blood to the body's tissues.

Cardiac - Pertaining to the heart.

Cardiac arrest - The stopping of the heartbeat, either the natural heart or an artificial heart.

Cardiac catheterization - A procedure that involves inserting a fine, hollow tube (catheter) into an artery, usually in the groin area, and passing the tube into the heart. Often used in conjunction with angiography and other procedures, cardiac catheterization has become a prime tool for visualizing the heart and blood vessels and diagnosing and treating heart problems.

Cardiac output - The amount of blood the heart pumps through the circulatory system in liters per minute.

Cardiology - The study of the heart and its function in health and disease.

Cardiopulmonary bypass - The process by which a machine is used to do the work of the heart and lungs so the heart can be stopped during surgery.

Cerebral embolism - A blood clot formed in one part of the body and then carried by the bloodstream to the brain, where it blocks an artery.

Cerebral hemorrhage - Bleeding within the brain resulting from a ruptured blood vessel, aneurysm, or a head injury.

Cerebral thrombosis - Formation of a blood clot in an artery that supplies part of the brain.

Cerebrovascular accident - Also called stroke. An impeded blood supply to some part of the brain, resulting in injury to brain tissue.

Collateral circulation - Blood flow through small, nearby vessels in response to blockage of a main blood vessel.

Computed tomography (CT or CAT scan) - An x-ray technique that uses a computer to create cross-sectional images of the body.

Congestive heart failure - A condition in which the heart cannot pump all the blood returning to it, leading to a back up of blood in vessels and accumulation of fluid in body tissues, including the lungs.

Coronary artery bypass (CAB) - Surgical rerouting of blood around a diseased vessel that supplies the heart by grafting either a piece of vein from the leg or the artery from under the breastbone.

Cuffs – AbioCor inflows used to sew onto the atria.

Deep vein thrombosis - A blood clot in the deep vein in the calf.

Diastolic blood pressure - The lowest blood pressure measured in the arteries, it occurs when the heart muscle is relaxed between beats.

Diuretic - A drug that lowers blood pressure by stimulating fluid loss; promotes urine production.

Doppler ultrasound - A technology that uses sound waves to assess blood flow within the heart and blood vessels and to identify leaking valves.

Dyspnea - A shortness of breath.

Echocardiography - A method of studying the heart's structure and function by analyzing sound waves bounced off the heart and recorded by an electronic sensor placed on the chest. A computer processes the information to produce a one-, two- or three-dimensional moving picture that shows how the heart and heart valves are functioning.

Edema - Swelling caused by fluid accumulation in body tissues.

Ejection fraction - A measurement of blood that is pumped out of a filled ventricle. Normal is 50 percent or more.

Embolus - Also called embolism; a blood clot that forms in the blood vessel in one part of the body and travels to another part.

Grafts – AbioCor outflow conduits that connects to the major arteries.

Heart failure - See congestive heart failure.

High blood pressure - Also called hypertension. A chronic increase in blood pressure above its normal range.

Hypotension - Abnormally low blood pressure.

Hypoxia - Less than normal content of oxygen in the organs and tissues of the body.

Implantation - Replacing a defective organ or tissue with an artificial device.

Infarct - The area of tissue permanently damaged by an inadequate supply of nutrients and oxygen.

Inferior vena cava - The large vein returning blood from the legs and abdomen to the heart.

Ischemia - Decreased blood flow to an organ, usually due to constriction or obstruction of an artery.

Ischemic stroke - A type of stroke that is caused by blockage in a blood vessel.

Lumen - The hollow area within a tube, such as a blood vessel.

Magnetic Resonance Imaging (MRI) - A technique that produces images of the heart and other body structures by measuring the response of certain elements (such as hydrogen) in the body to a magnetic field. When stimulated by radio waves, the elements emit distinctive signals in a magnetic field. MRI can produce detailed pictures of the heart and its various structures without the need to inject a dye.

Necrosis - Referring to the death of tissue within a certain area.

Noninvasive procedures - Any diagnostic or treatment procedure in which no instrument enters the body.

Paralysis - A condition of nerves or the brain that interferes with the ability to move parts of the body. The muscles do not receive signals to contract.

Parasympathetic nervous system - Part of the involuntary (autonomic) nervous system. Among other things, parasympathetic nerves slow the heart rate and cause blood vessels to dilate (open up).

Pericardium - The outer fibrous sac that surrounds the heart.

Physiological - How the functions of the body and its parts work, and the physical and chemical factors and processes involved in their working the way they do.

Platelets - One of the three types of cells found in blood; they aid in the clotting of the blood.

Pulmonary - Referring to the lungs and respiratory system.

Pulmonary embolism - A condition in which a blood clot that has formed elsewhere in the body travels to the lungs.

Renal - Pertaining to the kidneys.

Shock - A condition in which body function is impaired because the volume of fluid circulating through the body is insufficient to maintain normal metabolism. This may be caused by blood loss or by a disturbance in the function of the circulatory system.

Shunt - A connector that allows blood to flow between two locations.

Stenosis - The narrowing or constriction of an opening, such as a blood vessel or heart valve.

Sternum - The breastbone.

Stroke - Injury or death of cells in the brain, due to bleeding or blood clots that interfere with blood flow to a part of the brain. A stroke can cause the loss of sensation or the ability to move parts of the body, or it may affect memory, speech, swallowing, or other body functions. Severe strokes can be life-threatening and can cause death. Sometimes the effects of stroke are permanent; in other cases, some recovery of function is possible with rehabilitation and therapy.

Superior vena cava - The large vein that returns blood from the head and arms to the heart.

Sympathetic nervous system - Part of the involuntary (autonomic) nervous system. Among other things, sympathetic nerves speed up the heart rate and cause blood vessels to constrict (narrow down).

Syncope - Usually caused by an abnormal heart beat. A loss of consciousness as a result of temporary, insufficient blood supply to the brain.

Systolic blood pressure - The highest blood pressure measured in the arteries. It occurs when the heart contracts with each heartbeat.

Tachycardia - Accelerated beating of the heart.

Tachypnea - Rapid breathing.

Thrombolysis - The breaking up of a blood clot.

Thrombosis - A blood clot that forms inside the blood vessel or cavity of the heart, or in a device such as the AbioCor.

Thrombolytic therapy - Intravenous or intra-arterial drugs used to dissolve blood clots in an artery.

Transcutaneous Energy Transfer (TET) - A two-part skin transformer that transmits electrical energy across the intact skin.

Transesophageal echocardiography - A diagnostic test that analyzes sound waves bounced off the heart. The sound waves are sent through a tube-like device inserted in the mouth and passed down the esophagus (food pipe), which ends near the heart. This technique is useful in studying patients whose heart and vessels, for various reasons, are difficult to assess with standard echocardiography.

Transplantation - Replacing a defective organ with one from a donor.

Ultrasound - High-frequency sound vibrations, not audible to the human ear, used in medical diagnosis.

Vasodilators - Any medication that dilates (widens) the arteries.

Vasopressors - Any medication that elevates blood pressure.

Vein - Any one of a series of blood vessels of the vascular system that carries blood from various parts of the body back to the heart; returns oxygen-depleted blood to the heart.

Ventricle (right and left) - One of the two lower chambers of the heart.

Vertigo - A feeling of dizziness or spinning.

X-ray - Form of radiation used to create a picture of internal body structures on film or a digital camera.

AbioCor®

Implantable Replacement Heart System

PATIENT MANUAL

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July 2004
Document No. 0034-0980-00011 Rev. 1

Humanitarian Device. Authorized by Federal law for use in the treatment of patients with irreparably damaged hearts, at imminent risk of death with no other treatment options. The effectiveness of this device for this use has not been demonstrated.

IMPORTANT NOTICE: Read this ***entire*** manual before using the AbioCor Implantable Replacement Heart (AbioCor). The AbioCor is to be used only in accordance with this manual.

Information contained in this document is subject to change without notice.

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4 Operating the AbioCor System

5 Transferring Between Console and PCE Support

6 Alarms

Appendix Federal Communications Commission (FCC) Notice

Figures

Tables

Glossary

AbioCor Replacement Heart	system for patients with heart failure or another serious heart disease; takes the place of the natural heart to keep the blood flowing normally through the body
alternating current (AC)	normal household electrical power
antibiotic	medication used to treat infection
bpm	beats per minute; a measure of heart rate
cardiac output	the amount of blood that flows through your heart, expressed in liters per minute (L/min)
cardiopulmonary resuscitation (CPR)	a first-aid technique that uses pressure against the chest to restore the operation of a natural heart
Console	specialized computer that powers and controls the AbioCor System
diuretic	water pill
External Transcutaneous Energy Transfer coil (TET)	silicone ring containing a coil of wire; transfers energy from the Console to the implanted components of the AbioCor System
heart rate	the number of times per minute the Replacement Heart pumps blood
hydraulic fluid	liquid used to transmit energy; for example, the hydraulic fluid in automobile brake lines activates the brakes when the pedal is pushed against the fluid in the line
icon	a little picture used as a symbol
implanted	placed inside your body by a surgeon
Implanted Battery	AbioCor component that provides power to the Controller and the Replacement Heart

Implanted Controller	AbioCor component that manages the heart rate and stroke volume of the Replacement Heart to provide the needed blood flow
Implanted Transcutaneous Energy Transfer coil (TET)	AbioCor component that receives electrical energy through your skin from the External TET to keep your AbioCor System charged
L/min	liters per minute; a measure of cardiac flow
magnetic resonance imaging (MRI)	diagnostic technique that produces images of the inside of the body using electromagnetic energy
Patient-Carried Electronics (PCE)	portable system that provides battery power to the implanted AbioCor System through an External TET
PCE	see *Patient-Carried Electronics (PCE)*
precaution	information that alerts you to situations that carry a risk of minor injury to you, or situations in which the AbioCor Replacement Heart may malfunction or be damaged
Replacement Heart	AbioCor component that is implanted in your chest to pump blood to your lungs and other parts of your body
RF	radiofrequency; the type of communications signal used by the AbioCor System
RF Communications Module	external AbioCor component that sends data between the Console and the AbioCor Implanted Controller through the implanted RF Antenna
TET	transcutaneous energy transfer coil (implanted and external): transfers power from the Console to the implanted AbioCor System
Thoracic Unit	another name for the replacement heart
warning	information that alerts you to situations that can cause death or serious injury

Introduction

The AbioCor Replacement Heart is for patients with heart failure or another serious heart disease. It takes the place of your natural heart to keep the blood flowing normally through your body.

About this manual

This manual will help you understand how to live comfortably with your AbioCor Replacement Heart. The manual includes information about how the AbioCor System works in your body and how it fits into your daily routine. The manual also tells you how to adjust the system and when to call your doctor or clinic.

Manual overview

After you read this introduction, take a moment to browse through this manual, so you'll know where to find the information you need.

Section 1 lists important warnings and precautions to avoid potential safety problems and ensure that you get the best results from your AbioCor System.

Section 2 describes the parts of the AbioCor System and how they work together to keep your blood flowing normally. Some of these parts are inside your body, and others are outside of it.

Section 3 is about daily living with the AbioCor Replacement Heart. It tells how you can eat, sleep, exercise, shower, travel, and maintain other daily routines with the AbioCor System.

Section 4 tells how to connect and operate the external controls of the AbioCor System, using the Console.

Section 5 tells how to transfer control from the AbioCor Console to the Patient-Carried Electronics unit when you are going to be away from the Console.

Section 6 provides an overview of the AbioCor alarms that you might see or hear.

Definitions of special terms

This manual may use words that are new to you. Those terms are printed in bold type **(like this)** and defined in small notes in the margins near the paragraphs where they are used.

All these definitions are listed in alphabetical order in the Glossary at the front of this manual. The Glossary also includes abbreviations used in this manual.

1 Warnings and Precautions

This section contains two kinds of information.

- **Warnings** alert you to situations that can cause death or serious injury. The word "WARNING" and the symbol ⚠ appear before warning messages.
- **Precautions** alert you to situations that carry a risk of minor injury to you, or situations in which the AbioCor Replacement Heart may malfunction or be damaged. The word "CAUTION" and the symbol ⚠ appear before precaution messages.

Warnings

⚠ **WARNING:** Call your doctor or clinic immediately if the AbioCor System Console stops working.

If the Console stops working, connect the Patient-Carried Electronics (PCE) module to provide power immediately.

The AbioCor Replacement Heart will work for only about 30 minutes using its Implanted Battery power. After that, your AbioCor Replacement Heart must be connected to the Console or PCE for power. Otherwise, it will stop working, resulting in your death.

⚠ **WARNING:** If the External TET is removed, the AbioCor System runs on its Implanted Battery power, which only lasts for about 30 minutes. During this time, watch the Console for a low battery alarm and replace the external TET if a low battery alarm occurs.
When the Implanted Battery runs down, the AbioCor System will slow down, lowering your blood pressure. This might make you feel dizzy or faint. If the Implanted Battery runs down completely, the AbioCor System will stop working, resulting in your death.

magnetic resonance imaging (MRI): diagnostic technique that produces images of the inside of the body using electromagnetic energy

WARNING: Never undergo a **magnetic resonance imaging (MRI)** procedure.

The strong magnetic energy produced by an MRI machine may cause the AbioCor System to stop working.

cardiopulmonary resuscitation (CPR): a first-aid technique that uses pressure against the chest to restore the operation of a natural heart

WARNING: Never administer **cardiopulmonary resuscitation (CPR)** to a person who has an AbioCor Replacement Heart.

CPR will not work with an AbioCor Replacement Heart, and may cause life-threatening bleeding.

WARNING: Never travel to an altitude that is more than 2,500 feet higher or lower than the location at which the AbioCor Replacement Heart was implanted.

If emergency air transportation is needed, tell the pilot about the 2,500-foot restriction.

Changes in air pressure caused by altitude changes may cause the AbioCor Replacement Heart to work incorrectly, resulting in death or serious injury.

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WARNING: Do not allow any metal objects within 3 inches of the External TET while it is powered. Certain types of metal objects may quickly become extremely hot and present a burn or fire hazard.

WARNING: If you have an X-ray, the technician may put a lead shielding apron over your chest.

Put a thick pad (a Styrofoam® block or a folded towel at least 3 inches thick) between the AbioCor TET and the lead shielding apron, or remove the TET for a short time during the X-ray.

Without a thick pad, the AbioCor System components may get hot during the X-ray, causing a risk of a skin burn.

WARNING: Do not attempt to remove the Console cover or replace the Console Batteries.

Opening the cover could result in an electric shock. It could also result in damage that would cause the Console to operate incorrectly.

WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in your death.

Precautions

CAUTION: Do not block the cooling vents on the front of the Console while it is operating.

Blocked cooling vents may cause the Console to overheat and work incorrectly.

CAUTION: Disconnect the TET from the Console when it is not in use (for example, when you are using the Patient-Carried Electronics (PCE).

This precaution reduces the risk that the TET will be damaged by accidentally coming in contact with metal surfaces.

CAUTION: Keep the Console and PCE away from sources of electromagnetic radiation such as cell phones, 2-way radios, or appliances with electric motors if you observe signs of interference (for example, static on the phone or radio or on the AbioCor Console screen).

These devices may interfere with the AbioCor's communications system.

CAUTION: Do not use an electric blanket or heating pad when you have an AbioCor Replacement Heart.

Use of these products may cause incorrect operation of the AbioCor Replacement Heart or present a fire hazard.

CAUTION: Keep the TET cable outside your bed covers to prevent the cable from becoming too warm.

If the TET cable seems warmer than normal while you are using it, use a different TET and return the abnormally warm one to your doctor.

CAUTION: Never place a TET that is connected to the Console or PCE on a metal surface.

The TET may become overheated, causing a fire hazard.

CAUTION: Keep a TET that is connected to the Console or PCE at least 1 foot away from any other TET.

This precaution prevents potential damage to the TET's electronics.

CAUTION: Do not allow any liquids (including water) to come in contact with any electrical connector pins.

Contact with liquid may cause corrosion or electrical malfunction.

CAUTION: Do not clean the TET, Radiofrequency (RF) Communications Module, or cables with disinfectants that contain oxidizers such as iodine (Betadine® or similar disinfectants), hydrogen peroxide, hypochlorite (chlorine bleach), permanganate, or chromate.

These cleaners may break down the outer coverings of these AbioCor components.

CAUTION: Do not clean the TET, RF Communications Module, or cables with cleaners that may stain the surfaces you are cleaning. This staining may hide the breakdown of the outer coverings of these AbioCor components.

CAUTION: Never submerge any part of the PCE in liquid.

Liquids will severely damage the PCE and cause it to operate incorrectly.

CAUTION: Do not bend forward deeply from the waist. This posture might be uncomfortable because of the location of the Implanted Battery and Implanted Controller in your abdomen.

Bending forward may also affect the blood flow to your upper body, which may cause a momentary fainting spell.

CAUTION: Never try to disassemble the PCE, Battery Bag, or Batteries.

You may damage the PCE and cause it to operate incorrectly.

CAUTION: Never cover the PCE with clothing.

Covering the PCE may cause the PCE to overheat and operate incorrectly.

CAUTION: Never block the PCE's cooling vents.

Blocking the cooling vents may cause the PCE to overheat and operate incorrectly.

CAUTION: Never use a PCE Battery that has been dropped. It may not work correctly.

If you drop a PCE Battery, mark it *DO NOT USE* and return it to your doctor or clinic.

2 What is the AbioCor Replacement Heart?

The AbioCor Replacement Heart is for patients with heart failure or another serious heart disease. The AbioCor System was recommended for you because your heart disease put you at a high risk of death, and the disease could not be helped by any other treatment.

Implanted parts of the AbioCor System

The AbioCor Replacement Heart is **implanted** in your body, where it takes the place of your natural heart to keep the blood flowing normally through your body. The AbioCor System has four main parts that are implanted inside your body. These parts are shown in Figure 2.1.

implanted: placed inside your body by a surgeon

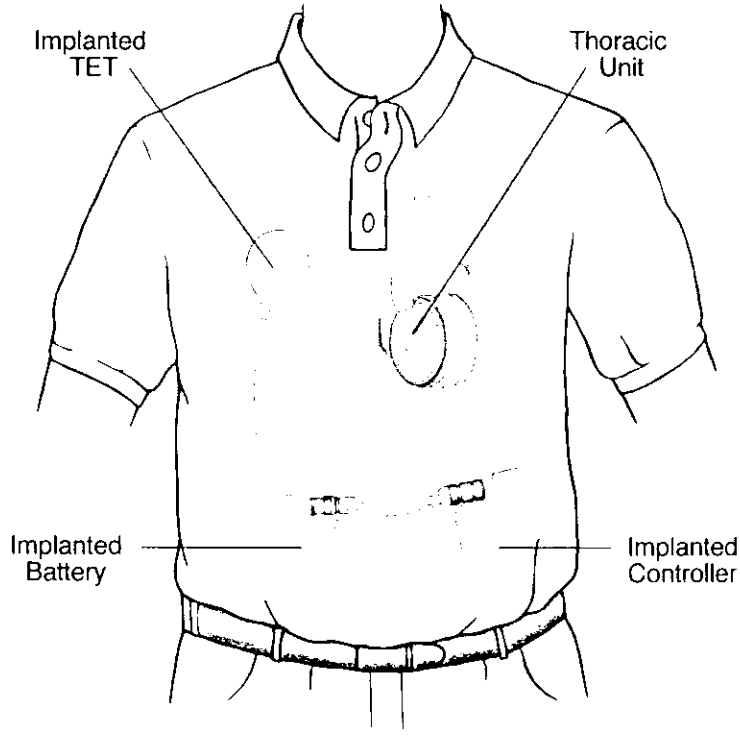

Figure 2.1 The Implanted Parts of the AbioCor System

Replacement Heart

The Replacement Heart (which is called the Thoracic Unit) is about the same size and shape as a natural heart and weighs a little over 2 pounds. It is implanted in your chest in place of your original diseased heart and connected to the blood vessels that supply blood throughout your body.

Figure 2.2 is a picture of the replacement heart.

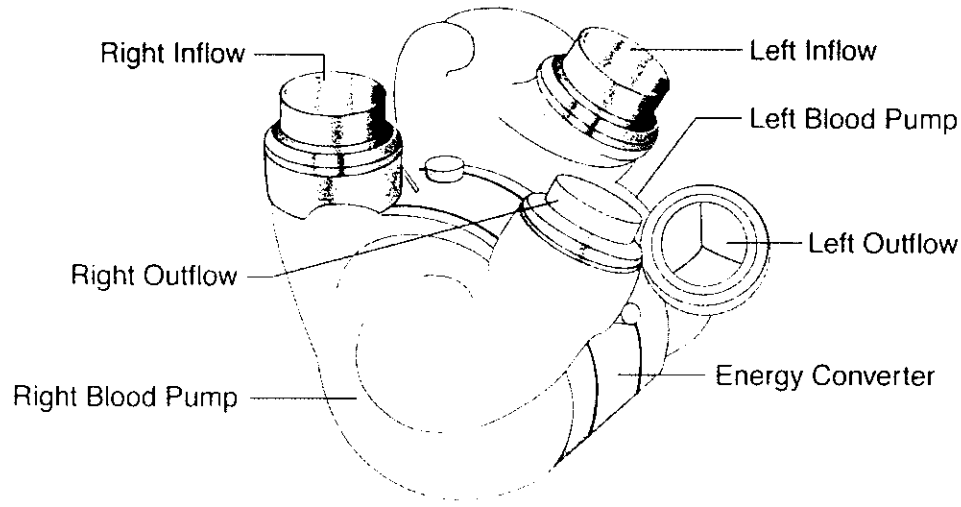

Figure 2.2 AbioCor Replacement Heart

The AbioCor Replacement Heart has right and left Blood Pumps that take turns pumping blood to the lungs and other areas of the body. These pumps are like balloons that fill with blood and then squeeze it out. Like the natural heart, each Blood Pump has an inflow opening for incoming blood and outflow opening for outgoing blood. These openings are connected to your own arteries and veins during the implant surgery.

An Energy Converter in the Replacement Heart helps the right and left blood pumps to keep blood flowing normally. The Energy Converter contains silicone **hydraulic fluid** in a sealed compartment. This compartment is separated from the right and left chambers by flexible membranes. A pump in the Energy Converter pushes the fluid against the membranes, causing the right and left blood pumps to empty and fill.

hydraulic fluid: liquid that is compressed to transmit energy; for example, the hydraulic fluid in automobile brake lines activates the brakes when the pedal is pushed against the fluid in the line

Implanted Controller

The Implanted Controller manages the **cardiac output** of the Replacement Heart to provide the needed blood flow. Most of the time, the Implanted Controller works automatically, but it can be operated manually by your doctor or nurse. The Implanted Controller is implanted in your abdomen at the same time as the Replacement Heart.

cardiac output: the amount of blood that flows through your heart, expressed in liters per minute (L/min)

The Implanted Controller monitors your system to make sure everything is working correctly. It also exchanges information with the Console and PCE to trigger an alarm if a problem occurs. The Implanted Controller settings can be adjusted from the Console; Section 4 of this manual tells how to do that.

Implanted Battery

The Implanted Battery provides power to the Controller and the Replacement Heart. Like the Controller, the Implanted Battery is placed in your abdomen when the Replacement Heart is implanted. The Implanted Battery is continuously charged through the skin by the External TET, which gets power from the Console or the PCE.

The Implanted Battery lasts for about a year, and can be replaced by your doctor during a simple surgical procedure. Your doctor monitors the status of your Battery to determine when it should be replaced.

Figure 2.3 shows the Implanted Battery and Implanted Controller.

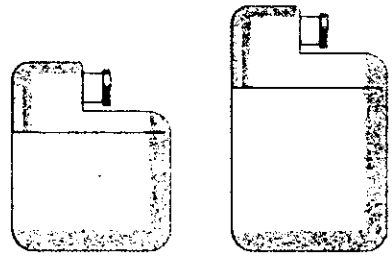

Figure 2.3 AbioCor Implanted Battery (left) and Implanted Controller (right)

Implanted TET

The Implanted TET is located under the skin, usually on your chest, and is shaped to conform to the shape of your body. The Implanted TET receives electrical energy through your skin from the External TET to keep your AbioCor System powered.

Figure 2.4 shows the Implanted TET.

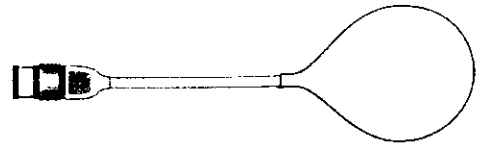

Figure 2.4 AbioCor Implanted TET

Implanted Cables

The implanted components are connected to each other by Cables. There is also an RF antenna for communications between the implanted AbioCor components and the Console.

Figure 2.5 shows the Implanted Cables.

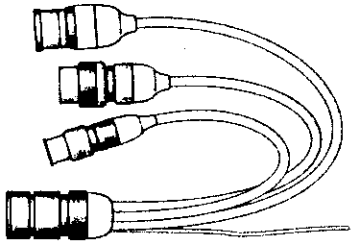

Figure 2.5 AbioCor Implanted Cables

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External parts of the AbioCor System

Your AbioCor System has some other external parts that work with the implanted components of the system. These external parts provide power to the AbioCor System, monitor its performance, and provide a way for you, your doctor, or your nurse to adjust the system when it's necessary. Some of the external parts of the AbioCor System are shown in Figure 2.6.

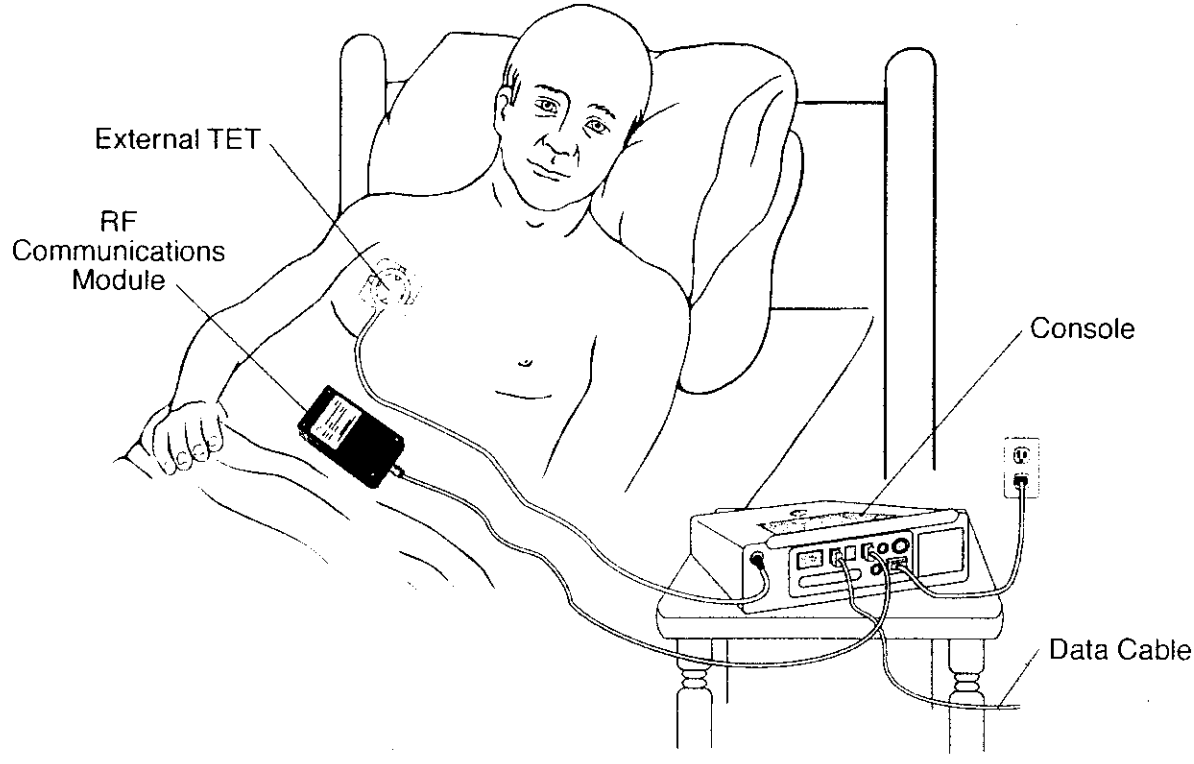


Figure 2.6 The External Parts of the AbioCor Replacement Heart

Console

The AbioCor Console is a specialized computer with a keypad and screen. It is plugged into a regular household electrical wall outlet to provide power to the AbioCor System through the Implanted TET and External TETs. The Console also contains a backup Battery that can supply power for 35 to 40 minutes if normal electrical power is interrupted.

The Console uses radio waves (like a cell phone) to send commands through the RF Antenna to the AbioCor Implanted Controller and to receive information from the Implanted Controller about how the Replacement Heart is functioning. The Console also notifies you with alarm lights and sounds if a problem occurs in your system.

Section 4 of this manual explains the buttons and other controls on the Console and tells how to use them.

Figure 2.7 is a picture of the Console lying flat. It can also be tilted up so you can see its display more easily by opening its fold-out stand.

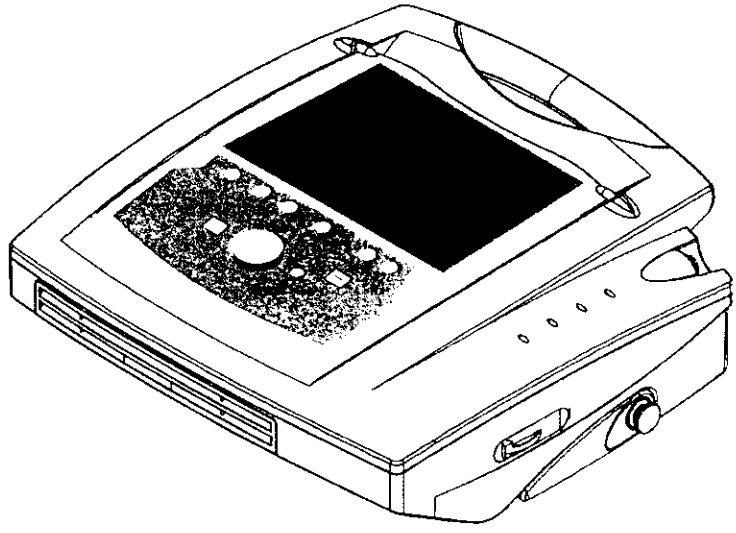


Figure 2.7 AbioCor Console (flat)

External TET

The External TET is a silicone ring containing a coil of wire. The External TET transfers energy from the Console to the implanted components of the AbioCor System. The energy flows from the Console to the External TET, across the skin, and into the Implanted TET. The Implanted TET distributes this energy to the implanted AbioCor System components.

The External TET is placed directly over the location where the Implanted TET is located. The External TET is held in place by a DuoDerm® patch with Velcro® fasteners, as Figure 2.8 shows. A cable connected to the External TET is plugged into the Console or PCE. Section 4 of this manual tells how to connect the External TET to the Console.

Two TET styles are available; one has a 5-foot cable and the other has an 11-foot cable. You can use the TET with the cable length that is more convenient for you at various times during the day.

Figure 2.8 is a picture of the External TET with its cable and a DuoDerm patch.

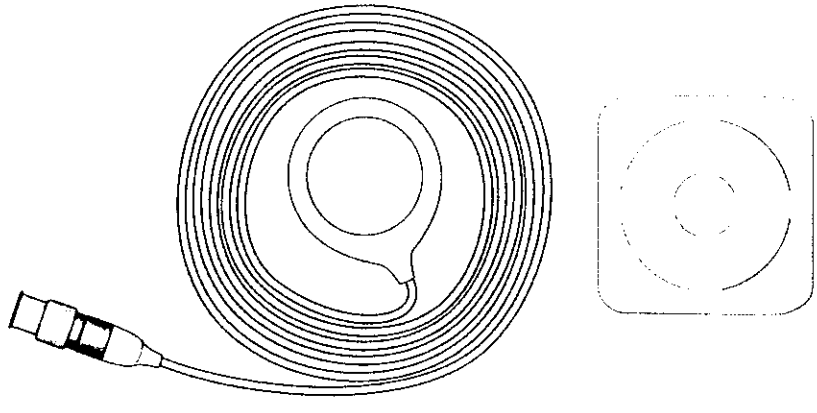


Figure 2.8 External TET with Cable and DuoDerm Patch

WARNING: If the External TET is removed, the AbioCor System runs on its Implanted Battery power, which only lasts for about 30 minutes. During this time, watch the Console for a low battery alarm and place the External TET on your chest if a low battery alarm occurs.

When the Implanted Battery runs down, the AbioCor System will slow down, lowering your blood pressure. This might make you feel dizzy or faint. If the Implanted Battery runs down completely, the AbioCor System will stop working, resulting in your death.

Radio frequency (RF) Communications Module

The RF Communications Module sends information between the Console and the AbioCor Implanted Controller through the implanted RF Antenna. This information includes commands from the Console to change AbioCor Replacement Heart settings and status information about the Replacement Heart, the Implanted Controller, and the Implanted Battery that goes back to the Console. The RF Communications Module plugs into the back of the Console. Section 4 of this manual tells how to connect the RF Communications Module to the Console.

Figure 2.9 is a picture of the RF Communications Module.

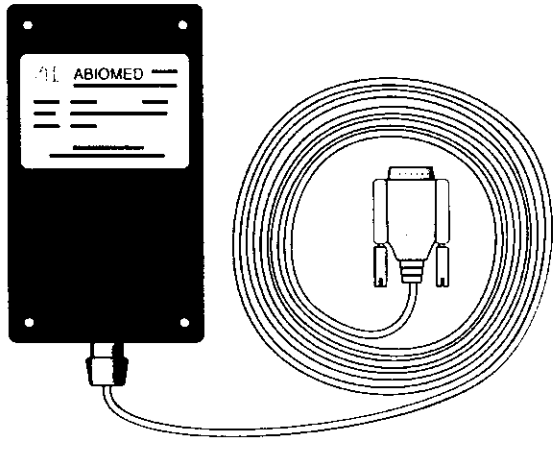


Figure 2.9 AbioCor RF Communications Module

Patient-Carried Electronics (PCE)

The Patient-Carried Electronics (PCE) is a portable system that provides battery power to the implanted AbioCor System through an External TET. (The TETs used with the PCE are the same as the ones used with the Console.) The PCE is carried in a nylon Battery Bag that you can wear over your shoulder. The PCE allows you to be mobile, away from the Console, for extended periods of time.

Figure 2.10 shows a picture of an AbioCor System user carrying the PCE.

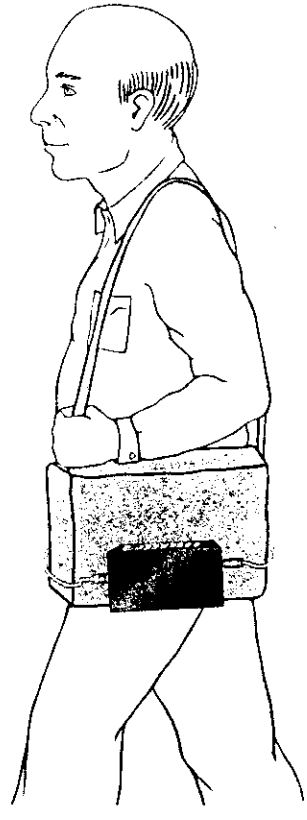


Figure 2.10 Using the Patient-Carried Electronics (PCE)

Like the Console, the PCE monitors your AbioCor System, using alarm lights and sounds to tell you if there is a problem with the system. The PCE is described in more detail in a separate manual.

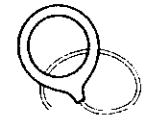
Section 5 of this manual tells how to transfer support between the Console and the PCE.

3 Living with the AbioCor System

Before you left the hospital with your new AbioCor Replacement Heart, your doctor or nurse gave you and your caregiver information about your daily routine with the AbioCor System.

The information in this manual is to help you remember what you learned. It is not a substitute for professional medical care. If anything in this manual is different from what your doctor or nurse told you, talk to your doctor or nurse and follow his or her advice.

Caring for your skin at the TET site



The skin under the DuoDerm patch and External TET may become irritated or damaged because it is always covered. Here are some tips for taking care of the skin in this area to prevent irritation or damage:

- Replace the DuoDerm patch if the edges begin to lift or become soiled.
- Check the skin under the DuoDerm patch and External TET when you change the DuoDerm patch.

  Call your doctor if the skin is sore, swollen, or if you notice skin discoloration such as bruising.
- Do not use any lotions, creams, salves, or powders on the skin under the DuoDerm patch unless your doctor or nurse tells you to do so.
- Clean the External TET and its cable, if needed, with a cloth moistened with alcohol. Do not let the connector (the end that plugs into the back panel of the AbioCor Console or the PCE Control Module) get wet.

Eating

A healthy, well-balanced diet is important to good health, and can help you recover faster from your implant surgery.

- Follow the guidelines given to you by the dietitian before you left the hospital.
- Call your doctor or nurse if your appetite goes away or decreases for a long time, or if you gain or lose more than two pounds in a week.
- If you have diabetes, check your blood sugar daily as you have been taught, and follow your doctor or nurse's advice about your medications.

Keeping track of your weight

Weigh yourself every day to be sure you are not retaining excess fluid. If you gain more than 2 pounds 2 days in a row, it could indicate that you are retaining excess fluid. If this happens, there is a chance your lungs could become overloaded, making it hard for you to breathe. Here some tips for keeping track of your weight:

- Weigh yourself at the same time every day, after urinating and before eating.
- Write down your weight every day.
- Call your doctor if you gain 2 pounds or more 2 days in a row. You may need a **diuretic;** or, if you are already taking one, you may need to have the dosage adjusted. Never change the dosage unless the doctor tells you to do so.

diuretic: water pill

- Also call your doctor if you *lose* 2 pounds or more 2 days in a row. Excess weight loss might indicate an unhealthy loss of fluid. Excess fluid loss will cause the AbioCor System to send out alarms.

Keeping track of your blood pressure

Take your blood pressure every day and write it down. Keeping track of your blood pressure helps determine how well the AbioCor System is performing. It also helps make sure the blood pressure medications you may be taking are working, and that the dosages are correct.

Taking your temperature

Increases in temperature can indicate an infection. This may mean you need an **antibiotic.** Take your temperature if you feel too warm, as if you might have a fever. Call your doctor if your temperature is higher than 101 degrees Fahrenheit or 38.5 degrees Celsius.

antibiotic: medication used to treat infection

Medication

Follow the directions you received from your doctor or nurse about taking your medications. Do not take any medicines—even those that do not need a prescription—without discussing it with your doctor. Some common medicines like aspirin or antacids can change the way your prescription medicines work.

Follow the same routine every day for taking your medicines. Keep a list of your medications and their dosages available at all times. If you leave home, take the medicines with you that you might need while you are gone.

Activities and rest

Keep a diary

Keep a diary to write down your activities and how they make you feel. This journal will to help you and your doctor see how well you are doing. Figure 3.1 shows what your journal might look like.

Date and time	Activity	How you felt
Tuesday 4/5/04 8 am	*Ate 1 piece of toast and 1 glass of orange juice.* *Took 1 blood pressure pill.*	*No problems*
Tuesday 4/5/04 noon	*Ate half of a turkey sandwich.*	*Not very hungry.*
Tuesday 4/5/04 1 pm	*Walked outdoors 5 minutes*	*Felt tired, but no dizziness*
Tuesday 4/5/04 4 pm	*Rode in car for 30 minutes*	*No problems*

Figure 3.1 Sample Diary Entry

The cardiac output of the AbioCor System can be adjusted to accommodate your activities. Your doctor or nurse can look at the AbioCor System's log and your journal to see how the AbioCor System is working for you.

Take rest breaks

Plan your daily activities so there are times to rest and relax throughout the day.

Sleep

Get plenty of sleep each night so that you will feel your best every day.

When you go to bed, use the AbioCor System Console instead of the PCE. Place the Console near your bed, with the RF Communications Module in place over your abdomen near the site of the Implanted Controller.

Subject to your consent, during part of the night while you are sleeping, the AbioCor Console is sending data from the AbioCor System log to ABIOMED. This information helps your doctor ensure that the AbioCor System is working at its best for you.

Here are some tips to make sure the AbioCor System does not interrupt your sleep:

- Be sure the DuoDerm patch is firmly attached to your skin. Change it if the edges are beginning to lift.
- Make sure the External TET is positioned directly over the Implanted TET and is firmly attached so it won't move when you turn in your sleep. Add more Velcro fasteners if necessary.
- Use the longer (11 foot) TET, so you can move around more easily in bed.
- While you are sleeping, your body does not need as much blood flow as it does while you are awake. Your doctor may give you instructions to lower your heart rate before going to bed. Section 5 of this manual tells how to change the heart rate on the AbioCor Console.
- Ordinarily, the AbioCor System will operate normally and will not sound an alarm if the RF Communications Module falls off your bed or otherwise loses contact with the Implanted Controller while you sleep. If a Heart alarm should occur, put the RF Communications Module near your abdomen again. This will allow the Console to display the details of the alarms and recommendations for what to do.

CAUTION: Do not use an electric blanket or heating pad when you have an AbioCor Replacement Heart.

Use of these products may cause incorrect operation of the AbioCor Replacement Heart or present a fire hazard.

CAUTION: Keep the TET cable outside your bed covers to prevent the cable from becoming too warm.

If the TET cable seems warmer than normal while you are using it, use a different TET and return the abnormally warm one to your doctor.

Exercise

Exercise is important for your overall well being. Research has shown that exercise reduces your blood pressure, helps control weight, decreases stress, and helps build strength and stamina.

Follow your doctor's advice about exercise. The AbioCor System will give you the blood flow you need as you increase the amount of exercise you can do comfortably. Consult your doctor if you are short of breath when you are exercising. He or she may tell you to increase the heart rate of the AbioCor System while you exercise.

CAUTION: Do not bend forward deeply from the waist. This posture might be uncomfortable because of the location of the Implanted Battery and Implanted Controller in your abdomen.

Bending forward may also affect the blood flow to your upper body, which may cause a momentary fainting spell.

Bathing or showering

General tips

After your doctor has said you can shower, you can bathe or shower as often as you wish. Always have someone at home with you when you take a bath or shower. Be sure that person knows you are taking a bath or shower so they can help you if needed.

Use a shower chair and ask for help from someone else if you feel unstable or dizzy when you stand. To avoid deep bends at the waist, use a long-handled brush to reach your back and legs.

Use warm water. Water that is extremely hot or cold can interfere with normal blood circulation and with your medications.

Clear the bathroom floor by removing any objects that might cause you to slip and fall.

Bathing or showering with the AbioCor System

Use the AbioCor PCE with the 11-foot TET cable while you bathe or shower, except for a few minutes when you clean your chest. Follow these tips for bathing or showering with your AbioCor System:

- Bring the PCE into the bathroom with you and put it in a safe place away from the bathtub or shower, where it is shielded from splashing. Do not get the PCE or any of the connections wet. These parts are not waterproof.

CAUTION: Do not allow any liquids (including water) to come in contact with any electrical connector pins.

Contact with liquid may cause corrosion or electrical malfunction.

- Leave the External TET in place while you wash all of your body except your chest. Then, remove your DuoDerm patch and TET while you wash your chest and dry off. It is safe to leave the TET off for about 10 minutes while you clean your chest and dry off. Place the TET on the bathroom floor or counter, or other non-metal surface.

CAUTION: Never place a TET that is connected to the PCE or Console on a metal surface.

The metal surface may become overheated, causing a fire hazard.

- After you dry off, put on a fresh DuoDerm patch and put the TET back on.

Taking trips away from home

WARNING: Never travel to an altitude that is more than 2,500 feet higher or lower than the location at which the AbioCor Replacement Heart was implanted.

If emergency air transportation is needed, tell the pilot about the 2,500-foot restriction.

Changes in air pressure caused by altitude changes may cause the AbioCor Replacement Heart to work incorrectly, resulting in death or serious injury.

Do the things you enjoy

It is important for you to get out and be active. Visit with friends, see movies, enjoy outdoor activities, go for walks, go to restaurants, go shopping— whatever activities you enjoy.

Below are some tips for safe and pleasant travel with your AbioCor System.

General information

- You can travel as a passenger by automobile. You should not drive a car yourself.
- Always have a family member or trusted friend who has been trained on the AbioCor System with you, so that you can get help quickly if you need it.
- Bring a cell phone with you so you can call for help in an emergency.
- Keep a list of your emergency contact names and numbers with you so you can call for help if you need it while you are away.

- Carry all the medications you might need to take while you are away from home.

- Keep a list of your medications and dosages in your wallet.

Power away from home for your AbioCor System

- Use the PCE to provide power to your AbioCor System when you travel. Information in Section 5 of this manual tells how to switch control of the AbioCor System from the Console to the PCE.

- If you will be outdoors, bring an umbrella to keep the PCE dry in case it rains.

- Charge your PCE Batteries every time you use them so they are always ready.

- Always carry enough Batteries to provide power for twice as long as you think you will be away from the Console. This strategy will ensure that you have enough Battery power in case you are delayed or have a problem with any of the Batteries.

- Take the AC Power Adapter for your PCE along with you if you will be gone for more than a few hours. The AC Adapter can be used to power your AbioCor System in place of the PCE Batteries if you are in a place with standard electrical power.

- If you will be more than 10 minutes from home by automobile, take your AbioCor Console with you. You will need the Console if it becomes necessary to make changes in the AbioCor System settings.

- Your vehicle should have an inverter or uninterruptible power supply (UPS) in it. These power sources can be used with the PCE's AC Adapter or with the Console.

Visits to your doctor

Your doctor will schedule routine checkups. It is important to keep your appointments with your doctor. Bring your medications and your records of blood pressure, weight, and activities with you. Your doctor will continue to monitor your condition, and will make changes to your medications if needed.

If you have an emergency

- ***If you have an emergency, first call your local emergency medical service.***

The paramedics and emergency medical technicians (EMTs) in your area have been given information about your medical condition and your AbioCor Replacement Heart. They will be able to help you.

- ***After you call the emergency medical service, call your doctor and tell him or her about the emergency.***

Your doctor or nurse should have given you a list of telephone numbers of people who are responsible for your care and safety. Post this list in a place where you, your family members, and other caregivers can see it at all times.

When to call your doctor

You may also need to consult your doctor or nurse for situations that are not emergencies. Call your doctor if:

- You have a temperature higher than 101 degrees Fahrenheit or 38.5 degrees Celsius

- You have redness, swelling, or pain at an incision or over the site of any of your implanted AbioCor components

- You retain excess fluids. Excess fluid retention might be the problem if you gain more than 2 pounds for 2 days in a row or you have increased swelling in your hands and feet, or become more short of breath
- You develop a cough that brings up thick yellow or bloody mucous
- You have difficulty taking your medication for any reason
- If you are not having an emergency, but you have a question about your medical condition or your AbioCor Replacement Heart
- If you have any new health problems, whether or not you think they are related to your AbioCor System
- If you are having problems with one of your AbioCor external components and think you need a replacement.

To speak to someone at ABIOMED

If you have questions regarding the AbioCor System, you can call someone at ABIOMED at any time, day or night.

- ***The ABIOMED phone number is 1-877-ABIOCOR (224-6267).***

You will have immediate access to someone who knows about you and the AbioCor System at all times.

4 Operating the AbioCor System

The AbioCor Console is the control center from which you manage the AbioCor System when you are not using the PCE.

The Console has a plastic cover to protect the display. You can flip the cover up to see the display. If you wish to remove the cover for easier viewing of the display, pull up on it at the center of the top (hinged) edge of the cover to flex it slightly. This will allow you to pull the cover gently out of its mounting holes.

The Console uses colored indicator lights to show you how all the parts of the system are working. You use the system keypad buttons and Selector Knob to work the system controls.

Setting up the Console

To set up the Console, place it on a firm surface such as a table or dresser top in a convenient place. To tilt the Console up so you can see it more easily, open the fold-out stand on the bottom of the Console. Be careful to allow plenty of air space around the cooling vents on the front of the Console.

CAUTION: Do not block the cooling vents on the front of the Console while it is operating.

Blocked cooling vents may cause the Console to overheat and work incorrectly.

Figure 4.1 shows the Console in its tilted-up position.

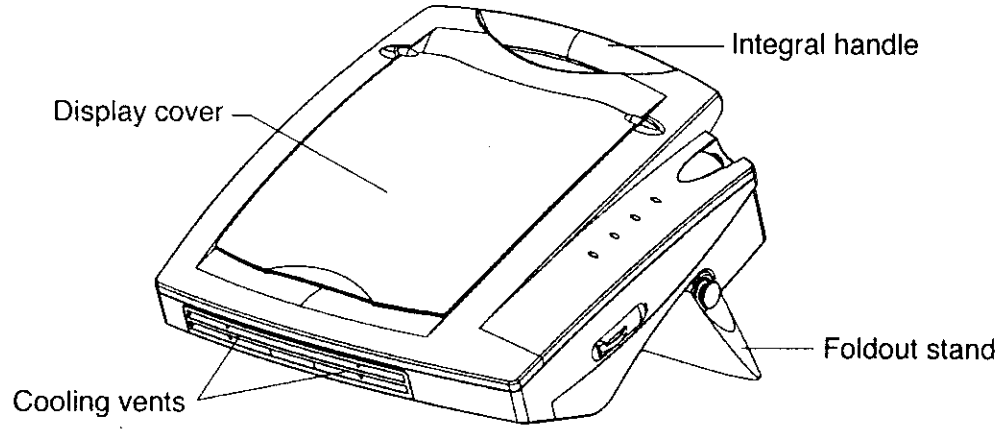


Figure 4.1 AbioCor Console (tilted)

Connecting the Console

Following the steps below, connect the power cord and the TET and RF Communications Module cables as shown in Figure 4.2.

1. Plug the External TET cable firmly into the round connector labeled TET, located above the indicator lights.

2. Plug the RF Communications Module cable into the connector on the back of the Console.

3. Plug the power cord into the Console and then into a wall outlet. The Console's cooling fan will come on as soon as the cord is plugged in, but the display screen will not light up until you turn on the Power switch.

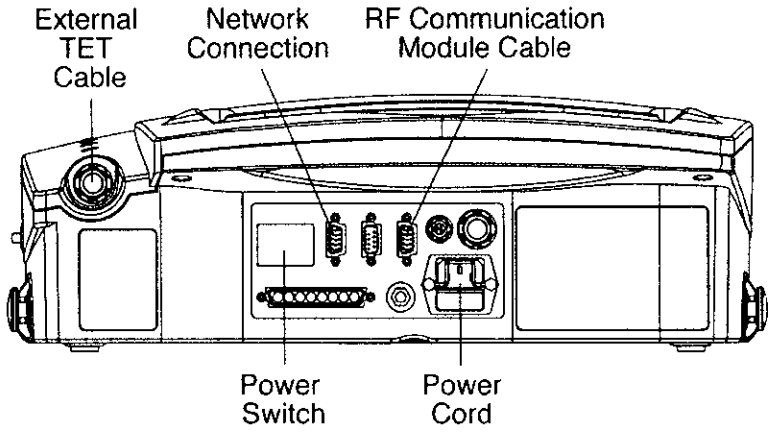


Figure 4.2 AbioCor Console Connections and Power Switch

Turning the Console ON

The Console Power switch is on the back panel, as shown in Figure 4.2. It is a white rectangular switch, protected by a clear plastic cover to keep the Console from being accidentally turned off.

To turn the Console on:

1. Flip the plastic cover up so that the Power switch is exposed.

2. Press the Power switch once.

   The Console's Power light comes on and the Console makes some clicking sounds as it goes through a self-test routine. The Console beeps to tell you the system is working correctly. The display on the front of the Console lights up and shows the Home Screen.

Information later in this section explains the Home Screen and tells you how to use the Home Screen to control your AbioCor System.

Indicator lights

Figure 4.3 shows the indicator lights on the Console.

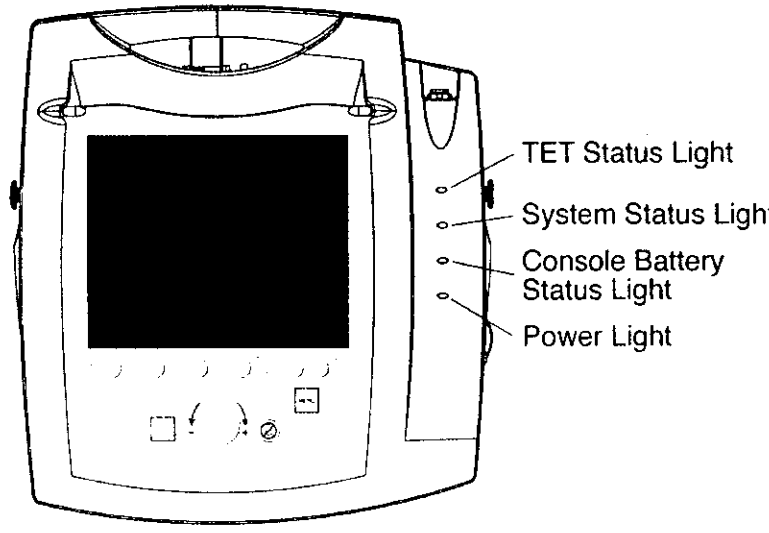


Figure 4.3 Console Indicator Lights

Table 4.1 explains what each of the Console indicator lights means.

Table 4.1 Console Indicator Lights

Indicator light	Color	Meaning
TET	Red	The External TET is not connected to the Console. If you are using the PCE, this condition is normal. If you are using the Console, plug the TET connector firmly into the round connector located above the indicator lights.
	Yellow	The TET is not powering the implanted Replacement Heart. If you are using the PCE, this condition is normal. If you are using the Console, be sure the External TET is firmly in position immediately over the Implanted TET.
	Green	The External TET is working correctly to power the implanted Replacement Heart.
System	Red	***There is a life-threatening problem with the implanted AbioCor Replacement Heart System.*** ***Call your doctor or nurse immediately.***
	Yellow	The implanted AbioCor Replacement Heart System needs attention. Be sure that the connectors from the TET and RF Communications Module are plugged in correctly. If the connections are correct and the light is still yellow, call your doctor or nurse.
	Green	The implanted system is working normally.
Battery	Yellow	The Console Battery is in use. Recharge the Console Battery soon by plugging the Console into a wall outlet.
	Green	The Console Battery is fully charged.
Power	Red	***The Console is running on Console Battery power.*** ***If possible, plug the Console into a wall outlet soon to keep the Console Battery charged.***
	Green	The Console is running on AC power (plugged into a wall outlet).

Buttons and controls

Figure 4.4 shows the buttons and Selector Knob on the Console.

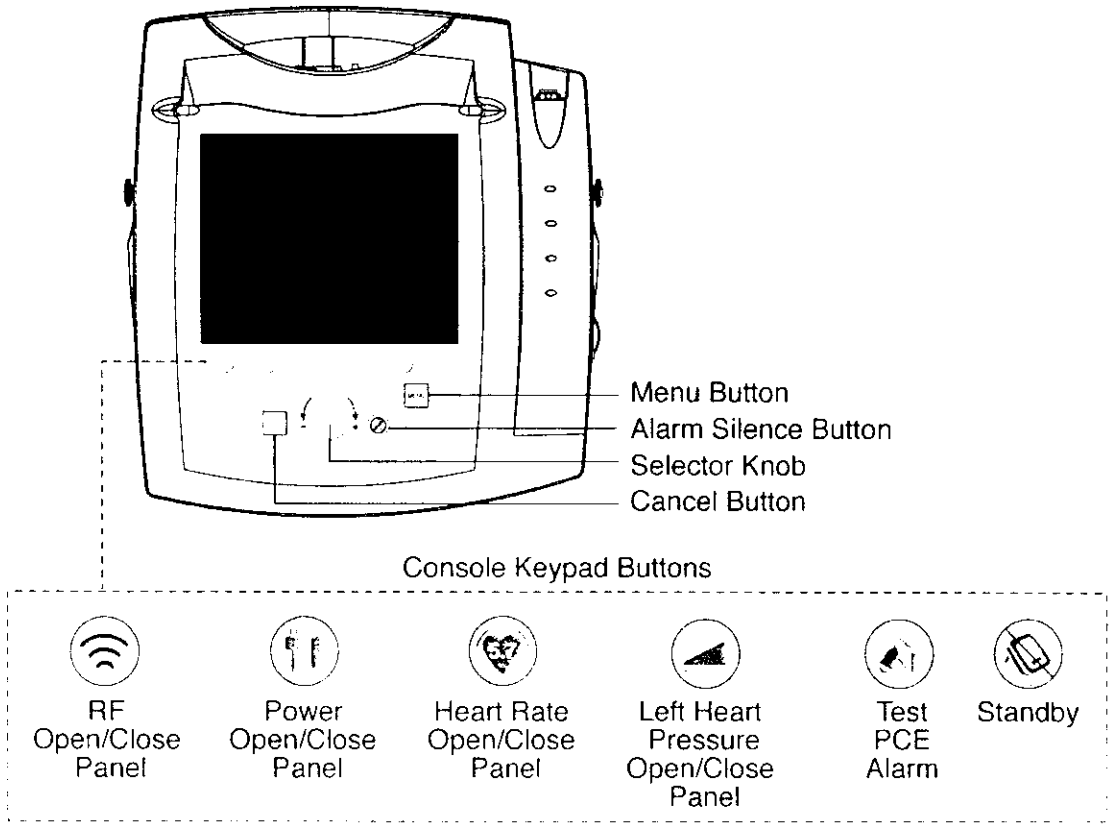
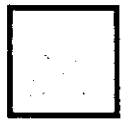


Figure 4.4 Console Buttons and Selector Knob

Table 4.2 tells how to use the Selector Knob and console keypad buttons.

Table 4.2 How to Use the Console Selector Knob and Buttons

Icon or label and name		How to use
Selector Knob		*Turn* the knob to locate the choice you want. *Press* the knob to select that choice.
MENU		The Menu button activates a menu on the display screen that is mostly used by your doctor or nurse. They need a password to use it. Your doctor may teach you to use the Menu button to use the "valve unstick" option on the Menu.
	Alarm silence	Press this button to temporarily turn off an audible alarm while you are resolving the cause of the alarm. If you are unable to resolve the alarm after two minutes, it will sound again. If a new alarm condition occurs, the sound will begin again immediately.
	Cancel	Press this button to cancel whatever you are doing without changing the AbioCor System settings.

The Home Screen

When you turn on the Console, the display shows the Home Screen. Figure 4.5 is an example of a Home Screen; depending on the settings of each System, the Home Screen may look different.

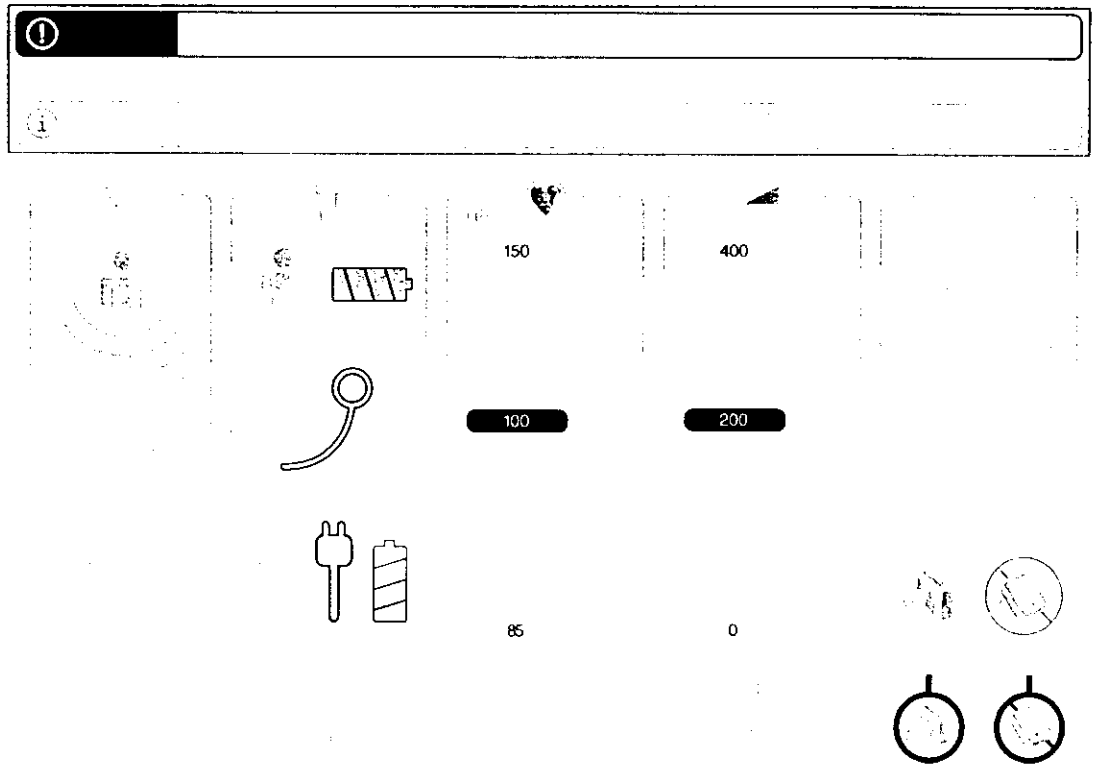


Figure 4.5 The Home Screen

The Home Screen is organized into sections, or panels. You use the different panels to look at the AbioCor System setup and make changes to the way the AbioCor System is working.

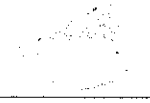
icon: a little picture used as a symbol

Each panel has an **icon** to show you what the panel is for.

- When a panel is closed, its icon on the display is green, above the soft button that controls it.
- When the panel is open, its icon is shown in gray at the top of the panel.

Table 4.3 shows the icon used to open each panel and tells what each panel is used for.

Table 4.3 Home Screen Icons

Area or Icon for panel	Name	What the Panel Does
	Alarms	System alarms are displayed across the top of the screen. • RED alarms are warnings about life-threatening problems. • YELLOW alarms are caution messages about serious problems. • WHITE alarms are messages to advise you of useful information. Alarm messages include telephone numbers that you should use to call emergency services and your doctor or nurse.
	RF	The RF panel shows the strength of the radio frequency (RF) communications signal between the Console and the implanted AbioCor System.
	Power	The Power panel shows which power source the AbioCor System is using and displays the status of three power sources: • the AC electrical power to the Console • the Implanted Battery • the Console Battery The Power panel also shows the status of the TET.
	Heart rate	The Heart Rate panel displays the heart rate range that the doctor has set for you. This panel also provides a way for you to adjust the heart rate of the AbioCor System. The number inside the heart on this icon is the current cardiac output of the AbioCor System, in liters per minute.
	Left Heart Pressure	The Left Heart Pressure panel displays the Left Heart Pressure setting. This panel also provides a way for you to adjust the left heart pressure setting.
	PCE alarm test	Press this button to confirm that the alarm system on the PCE is working correctly.
	Console Standby	Press this button to put the Console in standby mode. In standby mode, the Console is not actively controlling the AbioCor System. You might use this mode when you are using the PCE. The Console display asks for confirmation that you want to do this.

Turning the Console OFF

To turn the Console off:

1. Lift the plastic cover to expose the Power switch.

2. Press the Power switch once.

   The display shows a screen asking whether you want to turn off the Console, as shown in Figure 4.6.

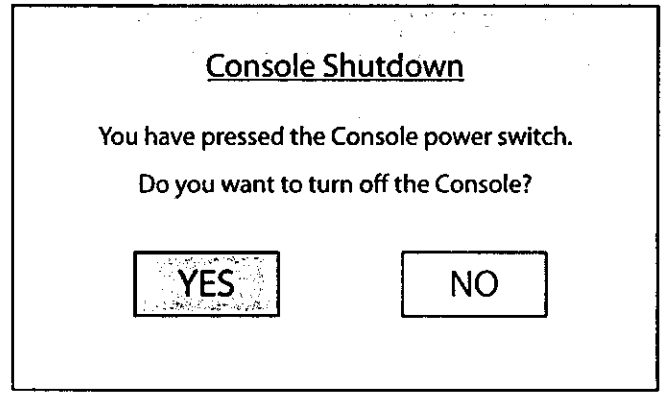


Figure 4.6 Console Shutdown Confirmation

3. Turn the Selector Knob to YES and press the knob.
   The system will shut down, but the Console fan will continue to run to cool off the Console.

If you do not want to turn the Console off:

1. Turn the Selector Knob to NO and press the knob.
   The display shows a screen like the one in Figure 4.7.

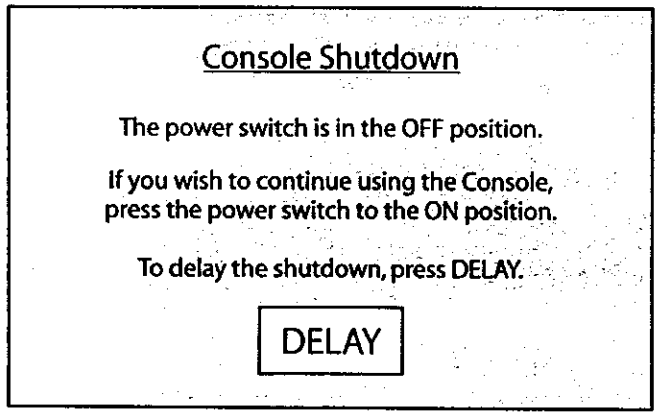


Figure 4.7 Console Shutdown Delay

2. To turn the Console on again, push the Power switch on the back panel.

To delay the shutdown for 2 minutes:

1. Turn the Selector Knob to choose DELAY and press it. After 2 minutes, the shutdown message shown in Figure 4.6 appears again.

2. Choose YES to turn the system off or NO to leave it on.

Viewing and changing information on the Home Screen

You can change some of the settings for your AbioCor Replacement Heart. Your doctor or nurse will teach you about when you may need to change a setting, and will show you how to do this. The information in this section will help you remember what you learned.

Table 4.4 lists some of the most likely changes you may need to make. It also tells which panel on the Home Screen you would use to make that change and the heading in this manual where you will find directions for making the change.

Table 4.4 Changing AbioCor Settings

Type of change	Panel	Heading in this Manual
Adjust the heart rate	Heart Rate	Adjusting your heart rate
Adjust the left heart pressure	Left Heart Pressure	Adjusting your left heart pressure setting

Opening panels

To open a panel, press the soft button that controls it on the Console keypad. For example, to open the Heart Rate panel, press the button below the Heart Rate icon.

Panels open automatically when an alarm condition occurs that affects that panel.

Selecting a panel for focus

The Selector Knob controls one panel at a time. When you open a particular panel, it comes into focus—that is, it becomes the panel that is controlled by the Selector Knob. The panel that is in focus has a green outline on the screen; the panels that are not in focus have a gray outline.

To put a different panel into focus, press the soft button below it.

The Alarm panel

The Alarm display

The Alarm panel, at the top of the Home Screen, displays text to tell you about any alarm conditions that occur. It looks like Figure 4.8.

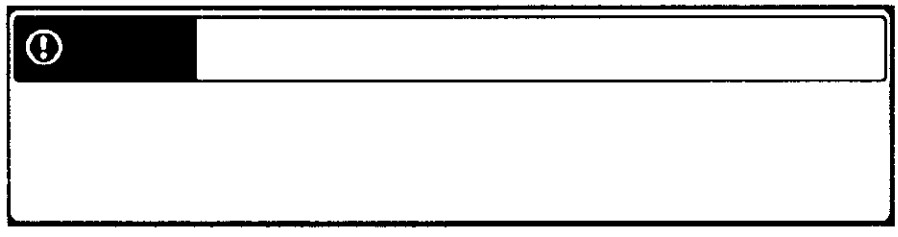


Figure 4.8 Alarm Panel

- RED alarms are warnings about life-threatening problems.
- YELLOW alarms are caution messages about serious problems.
- WHITE alarms are information alerts.

If the problem is resolved by itself (without you having to fix it), the alarm text stays on the screen for 10 minutes, or until you press the alarm silence button.

If you fix the problem that caused the alarm, the alarm text is cleared from the screen after you press the alarm silence button on the Console keypad.

Alarm sounds

Alarms are also announced by sounds. To quiet the alarm temporarily while you determine what needs to be done about it, press the alarm silence button on the Console keypad.

The alarm will be quieted for about 2 minutes. If the alarm has resolved, the message will go away.

The alarm will sound again if:

- the alarm condition still exists after 2 minutes
- a new alarm condition occurs

Different alarm sounds have different meanings, which are described in Section 6 of this manual.

Section 6 provides an overview of the AbioCor alarms that you might see or hear.

The RF panel

The RF panel on the Console shows the strength of the RF communications signal between the RF Communications Module plugged into the Console and the implanted AbioCor System. The panel uses colored arcs to show the strength of the signal.

Opening and closing the RF panel

To open the RF panel, press the soft button under the RF icon on the Home Screen.

The RF panel also opens automatically if an alarm occurs related to RF communications between the Console and the implanted AbioCor System components.

To close the RF panel, press the soft button under the RF icon on the Home screen. The panel will close unless there are unresolved alarms related to RF communication.

Understanding the RF panel

The RF panel uses colored arcs to show the status of RF communication between the Console and the implanted AbioCor System components. (See Table 4.5.)

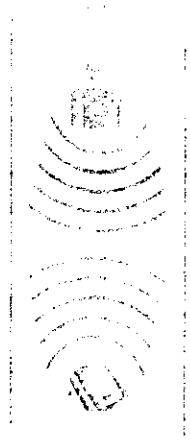
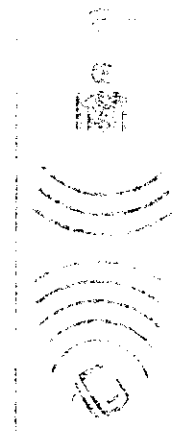
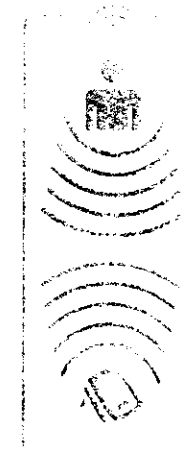
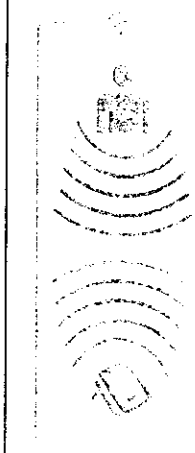
- Green arcs mean that RF communication is excellent.
- A combination of yellow and gray arcs means that there is a problem with RF communication.
- Gray arcs mean that no signal can be detected from the implanted AbioCor System components.

The arcs describe the quality of two signals:

- Arcs coming from the person icon on the RF panel represent the signal coming from the implanted AbioCor System to the Console (also called the outbound signal).
- Arcs coming from the Console icon represent the signal going from the Console to the implanted AbioCor System (also called the inbound signal).

Table 4.5 shows different examples of how the RF panel might look.

Table 4.5 RF Panel Displays of Signal Quality

				
Green arcs in both directions show excellent signal quality in both directions	Yellow and gray arcs coming from the person show a signal quality problem from the implanted AbioCor System. Green arcs coming from the Console show that communication from the Console is OK.	Yellow and gray arcs coming from the Console show a signal quality problem from the Console. Green arcs coming from the person show that communication from the implanted AbioCor System is OK.	Gray arcs coming from the person show that no signal is detected from the implanted AbioCor System. Green arcs coming from the Console show that communication from the Console is OK.	Gray arcs coming from the Console show that no signal is detected from the Console. Green arcs coming from the person show that communication from the implanted AbioCor System is OK.

How the RF signal affects the AbioCor System's performance

The AbioCor's implanted parts continue to work correctly if there is a weak or missing RF signal, using the most recent settings that it received from the Console. The Console displays the most recent information that it received from the implanted parts, which may not be current. Panels on the display have a speckled gray background (to represent static) if the RF signal is weak or missing.

The Console display is updated when a strong RF signal is restored. The RF signal strength is ordinarily not a cause for concern. However, make sure there is a good RF signal when you need to change an AbioCor System setting (such as heart rate).

If the RF panel shows poor signal quality

If the RF panel shows poor signal quality, try these steps to improve the quality of the RF signal.

1. Move the RF Communications Module and try to place it closer to the implanted Controller, which has a built-in RF Antenna. Watch the RF panel display to see if the signal quality improves.

2. Be sure that the RF Communications Module is plugged securely into the back of the Console.

3. Check for electrical equipment nearby (such as vacuum cleaners, radios, or power tools) that might be interfering with AbioCor signals. Turn off the equipment and see if the signal improves.

4. If these steps do not improve RF signal quality, replace the RF Communications Module and return the old one to your doctor.

The Power panel

The Power panel on the Console shows which power source the AbioCor System is using and the status of the three power sources:

- the AC electrical power to the Console
- the Implanted Battery
- the Console Battery

The Power panel also shows the status of the TET.

Opening and closing the Power panel

To open the Power panel, press the soft button under the Power icon on the Home Screen.

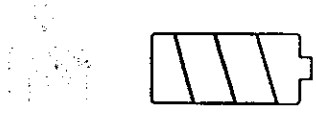
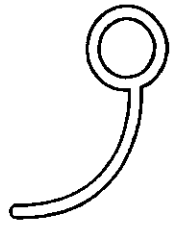
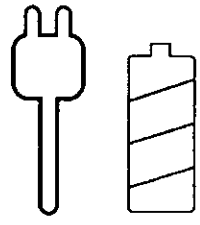
The Power panel also opens automatically if an alarm occurs related to the power sources of the Console, the Implanted Battery, or the TET. The Power panel also opens if the TET is misaligned.

To close the Power panel, press the soft button under the power icon on the Home Screen. The panel will close unless there are unresolved alarms related to power sources.

Understanding the Power panel

The information on the Power panel is divided into three sections, as shown in Table 4.6.

Table 4.6 Console Power Panel Layout

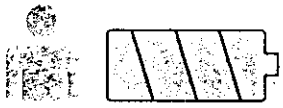
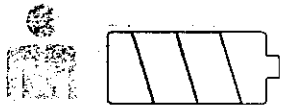
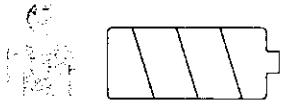
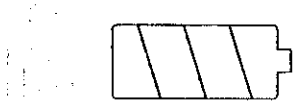
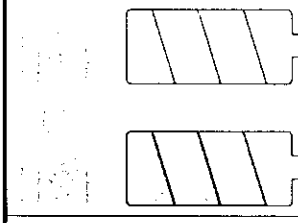
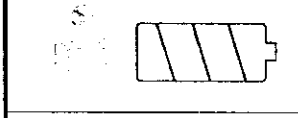
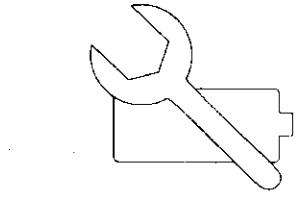
	Implanted Battery status	The top section of the Power panel, with icons of a person and a Battery, shows the status of the Implanted Battery. The Implanted Battery is shown lying on its side. In this example, the Implanted Battery is surrounded by a halo (outline), indicating that it is supplying power to the AbioCor Replacement Heart. The Implanted Battery is ¾ green, showing that is nearly fully charged.
	TET alignment	The middle section of the Power panel shows the status of the External TET. In this example the icon of the External TET is yellow and does not overlap the gray Implanted TET, showing that the TET is misaligned.
	Console power status (AC and Battery)	The bottom section of the Power panel shows the status of the Console's two power sources: ▪ AC power, shown as a power plug ▪ the Console Battery, shown as a battery standing upright In this example, the power plug is surrounded by a halo, showing that it is in use. The Console Battery is gray and not surrounded by a halo, showing it is not in use. All the sections of the Console Battery are filled in, showing it is fully charged.

Inside each section, symbols and colors show the status of each power source.

Implanted Battery symbols

Table 4.7 explains the symbols used for the Implanted Battery on the Power panel.

Table 4.7 Implanted Battery Symbols on the Power Panel

	• The Implanted Battery is in use (indicated by a halo around the battery). • The Implanted Battery is fully charged (indicated by all sections filled in).
	• The Implanted Battery is in use (halo around battery). • The Implanted Battery is about ¾ charged (indicated by 3 of 4 sections filled in).
	• The Implanted Battery is in use (halo around battery). • The Implanted Battery's charge is low (yellow).
	• The Implanted Battery is in use (halo around battery). • The Implanted Battery's charge is critically low (red).
	• The Implanted Battery is not in use (gray color and no halo). • The Implanted Battery is fully charged.
	• The Implanted Battery is not in use (gray, no halo). • The Implanted Battery is charging. • This icon flashes the battery symbol from empty (all white) to nearly full (1, 2, or 3 sections gray) as it charges.
	• The Implanted Battery status cannot be detected because the RF signal quality is poor (indicated by a gray speckled background in the area surrounding the icons).
	• The Implanted Battery has a charging failure. • If the charge status is not known, the wrench symbol appears over an outline of a battery. • If the charge status is known, the wrench appears over a green, yellow, or red battery as shown above.

Implanted Battery life

The Implanted Battery will work for approximately 30 minutes when the External TET is removed.

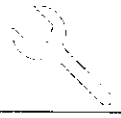
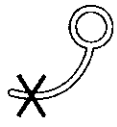
The Implanted Battery lasts for about a year, and can be replaced by your doctor during a simple surgical procedure. Your doctor monitors the status of your Implanted Battery to determine when it should be replaced.

Note: Exercise the Implanted Battery once every week to help maintain its capacity. This means allowing the Battery to discharge and charge. See the procedure at the end of this section for information about how to exercise the Battery.

TET symbols

Table 4.8 explains the symbols on the TET section of the Power panel.

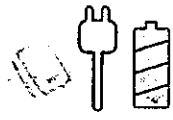
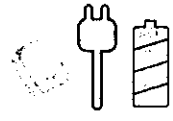
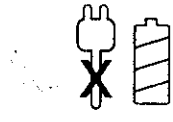
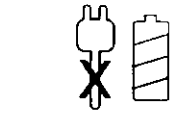
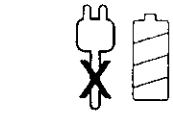
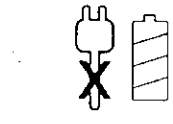
Table 4.8 TET Symbols on the Console Power Panel

	• The External TET is aligned with the Implanted TET well enough to power the AbioCor System and charge the Implanted Battery.
	• The External TET is misaligned with the Implanted TET. • Move the External TET to align it with the Implanted TET.
 	• The TET has a life-threatening problem. • Use a spacer (such as a folded wash cloth) to locate the External TET farther away from the Implanted TET until the wrench turns yellow. • Then, secure the External TET at the new location (with the spacer in place) and call your doctor.
	• The TET is not plugged in. • This icon appears on the screen if you are being supported by the PCE. • If you are being supported by the Console, plug the TET firmly into its connector.

Console Power and Battery symbols

Table 4.9 explains the symbols used on the Console power and battery section of the Power panel.

Table 4.9 Console Power and Console Battery Symbols on the Power Panel

	• The Console is running on AC power (indicated by halo around power plug). • The Console Battery is not in use (gray color), but is fully charged (all sections filled)
	• The Console is running on AC power (halo around power plug). • The Console Battery is not in use (gray color), and is about half charged (two sections filled).
	• The AC power is unplugged (indicated by plug with an X through it). • The Console Battery is in use (indicated by a halo surrounding the battery). • The battery is fully charged (all sections filled in).
	• The AC power is unplugged (plug with an X through it). • The Console Battery is in use (halo surrounding the battery). • The Console Battery is ¾ charged (indicated by 3 of 4 sections filled in).
	• The AC power is unplugged (plug with an X through it) • The Console Battery is in use. • The Console Battery's charge is low (indicated by yellow color, 2 sections filled in). • If possible, plug the Console into AC power. Otherwise, transfer support to the PCE.
	• The AC power is unplugged (plug with an X through it) • The Console Battery is in use (halo surrounding the battery). • The Console Battery's charge is critically low (indicated by yellow color, only one section filled in). • If possible, plug the Console into AC power. Otherwise, transfer support to the PCE.
	• The Console Battery has a charging failure. • Switch to a backup Console or PCE and ask your doctor to provide you with a new Console.

The Heart Rate panel

The Heart Rate panel on the Console does three things:

- shows the **cardiac output** (the number in the center of the heart rate icon)
- shows the rate at which the Replacement Heart is beating
- gives you a way to adjust the AbioCor System's heart rate within the range set by your doctor.

cardiac output: the amount of blood that flows through your heart, expressed in liters per minute (abbreviated as L/min); a liter is about 34 ounces, a little more than a quart

Why Does the AbioCor System Need a Heart Rate Adjustment?

In the AbioCor System, cardiac output is controlled by the Heart Rate setting. From time to time, this setting may need to be changed because of your medical condition or changes in your activity level. By adjusting the heart rate on the AbioCor System, you can increase or decrease the rate at which blood flows through your body.

Opening and closing the panel

To open the Heart Rate panel, press the soft button under the heart rate icon on the Home Screen.

The Heart Rate panel also opens automatically if an alarm occurs related to the heart rate.

To close the Heart Rate panel, press the soft button under the heart rate icon on the Home Screen. The panel will close unless there are new settings to be sent to the AbioCor System or there are unresolved alarms related to the heart rate.

Understanding the Heart Rate panel

The Heart Rate panel displays the range that your doctor has set for your heart rate, based on your medical condition, activity level, and other factors.

Figure 4.9 identifies the numbers on the Heart Rate panel. The numbers stand for the number of beats per minute. The values shown in the picture are examples; your own heart rate range and setting and your actual heart rate may be different.

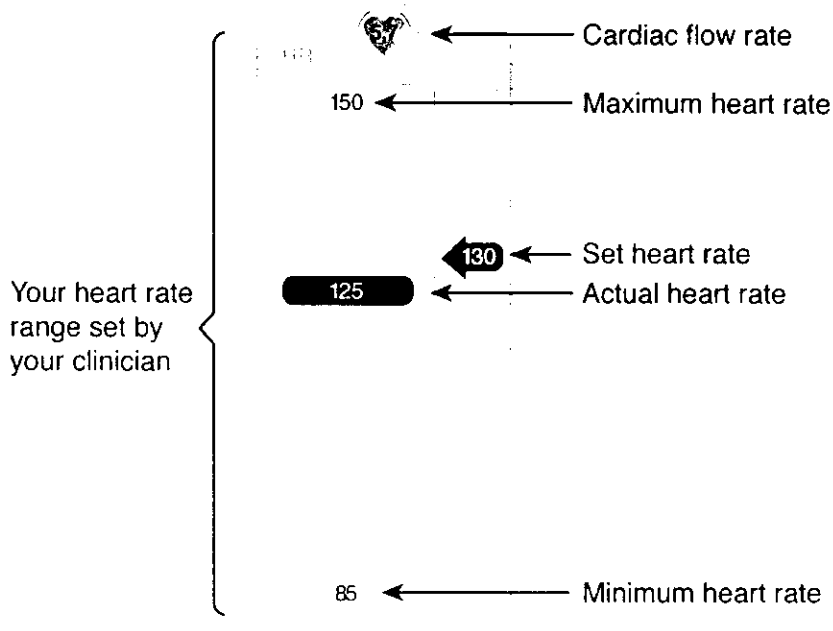


Figure 4.9 Heart Rate Panel

Table 4.10 explains the numbers used in the Console Heart Rate panel.

Table 4.10 Numbers on the Heart Rate Panel

Heart rate range	• The heart rate range is set by your doctor based on your medical condition and your level of activity. In this example, the range is from 85 to 150 beats per minute (bpm). • Only your doctor can change your heart rate range.
Cardiac output	• In this example, the rate of 5.7 liters per minute (L/min) means that 5.7 liters of blood are passing through each side of the heart every minute. • The cardiac output may change as a result of changes in your blood pressure or under certain conditions such as using your Implanted Battery. • The cardiac output changes when the heart rate is changed.
Maximum heart rate	• This is the highest rate at which the AbioCor Replacement Heart will beat; this rate is set by your doctor. • In this example, the maximum heart rate is 150 bpm.
Set heart rate	• This is the rate at which the AbioCor System is set to operate. In this example, the rate is set at 130 bpm. • If the set rate is the same as the actual rate, the set rate does not appear. • Your doctor may teach you how to set the heart rate for special needs— for example, to provide a higher rate of blood flow for exercise or a lower rate for sleep. • You can only adjust the heart rate within the range set by your doctor.
Actual heart rate	• This is the rate at which your AbioCor Replacement Heart is beating. In this example, the actual heart rate is 125 bpm. • The actual heart rate may be different than your set heart rate because of a number of factors, including: (1) You are using the Implanted Battery, and (2) Certain alarm conditions are active.
Minimum heart rate	• This is the lowest rate at which your AbioCor Replacement Heart will beat; this rate is set by your doctor. • In this example, the minimum heart rate is 85 bpm.

Adjusting your heart rate

To adjust your heart rate, if your doctor has instructed you to do so, follow these steps.

1. Open the RF Panel and check the RF communications signal. You need good RF signal quality in both directions in order to change the Heart Rate setting.

2. Open the Heart Rate Panel.

3. Turn the Selector Knob clockwise (to the right) to increase your heart rate, or counterclockwise (to the left) to decrease it.

4. Press the Selector Knob to send your new heart rate selection to the AbioCor Implanted Controller.

5. The new Heart Rate setting will change slowly. It will be displayed in the blue and white arrow in the Heart Rate panel.

6. If the actual heart rate does not match the set heart rate, you may be using the Implanted Battery, or there may be active alarms overriding your change.

The Left Heart Pressure panel

The Left Heart Pressure panel on the Console does two things:

- displays the current setting of the left heart pressure
- provides a way for you to adjust the left heart pressure

You can adjust the left heart pressure setting if your doctor instructs you to do so.

Why Does the AbioCor System Need a Left Heart Pressure Adjustment?

The right and left sides of your natural heart pump different amounts of blood. To simulate your natural heart, the AbioCor must also pump different amounts of blood from the right and left sides.

If the AbioCor pumps too much blood on the right side (compared to the left side), you could experience shortness of breath.

If the AbioCor pumps too little blood on the right side, AbioCor alarms could result.

Opening and closing the panel

To open the Left Heart Pressure panel, press the soft button under the left heart pressure icon on the Home Screen.

The Left Heart Pressure panel also opens automatically if an alarm occurs related to left heart pressure.

To close the Left Heart Pressure panel, press the soft button under the left heart pressure icon on the Home Screen. The panel will close unless there are new settings to be sent to the AbioCor System or there are unresolved alarms related to left heart pressure.

Understanding the Left Heart Pressure panel

The Left Heart Pressure panel displays the current setting of the Left Heart Pressure. This setting is within a range from 0 to 400. The numbers do not stand for anything specific; they are just a way to describe the pressure setting of the left heart pump. If the current Left Heart Pressure setting is the same as the Left Heart Pressure level that has been set, the set level does not appear.

Figure 4.10 shows the Console Left Heart Pressure panel during the process of adjustment.

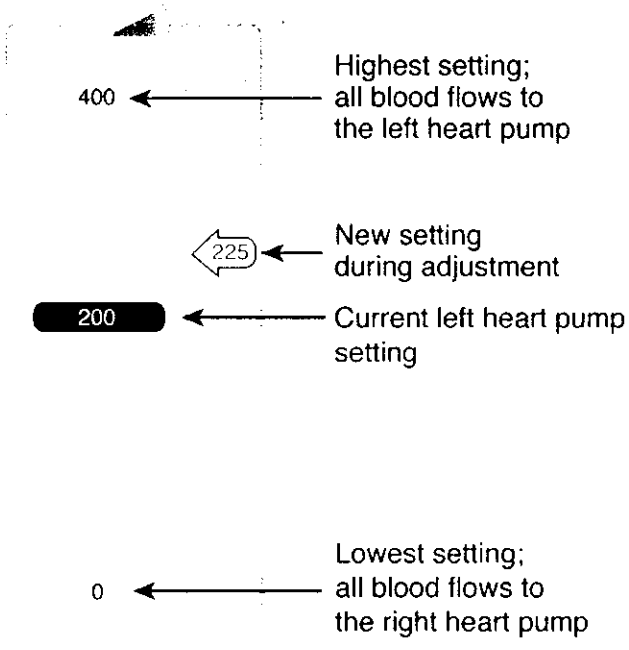


Figure 4.10 Left Heart Pressure Panel

Adjusting your Left Heart Pressure setting

To adjust your Left Heart Pressure setting, if your doctor has instructed you to do so, follow these steps.

1. Open the RF Panel and check the RF communications signal. You need high RF signal quality in both directions in order to change the Left Heart Pressure setting.

2. Open the Left Heart Pressure panel.

3. Turn the Selector Knob to choose a new Left Heart Pressure setting (clockwise to increase the value, counter-clockwise to decrease it).

4. Press the Selector Knob to send your new Left Heart Pressure selection to the AbioCor Implanted Controller.

The Menu panel

The Menu button activates the menu panel on the display screen that is primarily used by your doctor or nurse. They need a password to use it.

Exercising your Implanted Battery

Exercise your Implanted Battery once a week to help maintain its capacity. You may do this during a routine doctor's appointment, but it is possible you will need to do it at home, too.

Here is how to exercise the battery:

1. Be sure the Implanted Battery is fully charged.

2. Have a caregiver or trusted friend with you during this procedure.

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3. Sit or lie down.

4. Unplug the External TET from the AbioCor Console or PCE that you are using.

5. Have your caregiver closely monitor you and the AbioCor System for any changes. If any signs of distress occur (for example, dizziness or shortness of breath), immediately reconnect the Console TET.

6. Leave the External TET disconnected for 30 minutes or until the alarm is activated.

7. After 30 minutes, reconnect the External TET to the AbioCor Console or PCE.

8. Repeat this procedure to exercise the Battery once every week.

Cleaning the AbioCor System

Precautions

CAUTION: Do not clean the TET, Radio frequency (RF) Communications Module, or cables with disinfectants that contain oxidizers such as iodine (Betadine® or similar disinfectants), hydrogen peroxide, hypochlorite (chlorine bleach), permanganate, or chromate.

These cleaners may break down the outer coverings of these AbioCor components.

CAUTION: Do not clean the TET, RF Communications Module, or cables with cleaners that may stain the surfaces you are cleaning. This staining may hide the breakdown of the outer coverings of these AbioCor components.

CAUTION: Do not allow any liquids (including water) to come in contact with any electrical connector pins.

Contact with liquid may cause corrosion or electrical malfunction.

To clean your AbioCor System, see the tips below.

Cleaning the Console

Clean the Console display and case when they become dusty or soiled.

To clean the Console display, wipe it with a soft cloth slightly moistened with isopropyl (rubbing) alcohol.

To clean the Console case, wipe it with a soft cloth moistened with a mild detergent solution.

Cleaning the External TET, RF Communications Module, and Cables

Clean the External TET, RF Communications Module, and Cables once every day, as described here:

1. Clean the External TET, RF Communications Module, and Cables with a soft cloth slightly moistened with isopropyl alcohol.

2. Wipe the External TET, RF Communications Module, and Cables with a soft cloth moistened with water or a mild detergent solution.

5 Transferring Between Console and PCE Support

WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

CAUTION: Never cover the PCE with clothing.

Covering the PCE may cause it to overheat and operate incorrectly.

CAUTION: Never block the PCE's cooling vents.

Blocking the cooling vents may cause the PCE to overheat and operate incorrectly.

CAUTION: Keep a TET that is connected to the Console or PCE at least 1 foot away from any other TET.

This precaution prevents potential damage to the TET's electronics.

CAUTION: Never place a TET that is connected to the Console or PCE on a metal surface.

The TET may become overheated, causing a fire hazard.

Transferring Support from the Console to the PCE

When you want to use the PCE instead of the Console, follow the step-by-step procedure listed below. These procedures will ensure that the PCE works correctly to provide energy to your implanted AbioCor Replacement Heart.

There are two different procedures:

- one procedure for using the same TET with the PCE as you use with the Console
- another procedure for changing TETs when you transfer support to the Console

Transferring to the PCE if You Use the Same TET

If you want to use the same TET with the PCE as with the Console, follow this procedure.

1 Insert 2 pairs of fully-charged Batteries into slots in the Battery Bag as shown in Figure 5.1.

- Be sure that the Battery pair indicator lights between the Battery slots in the PCE Battery Bag (Figure 5.1) turn on when the Batteries are in place.
- If the indicator lights do not turn on, be sure the Batteries are plugged securely into place.
- The PCE alarm will sound.

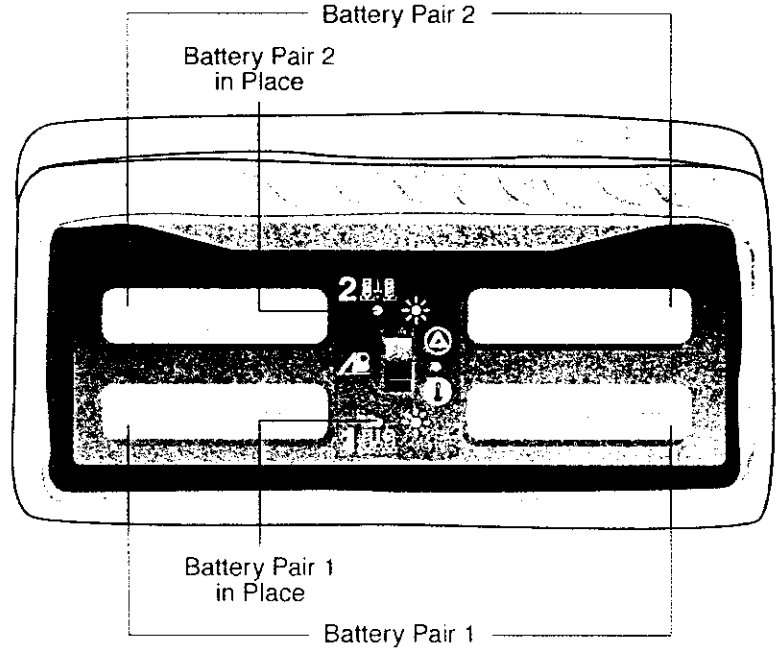

Figure 5.1 Installing Batteries in the Battery Bag

2 Plug the Battery Cable on the Battery Bag into the PCE Control Module as shown in Figure 5.2.

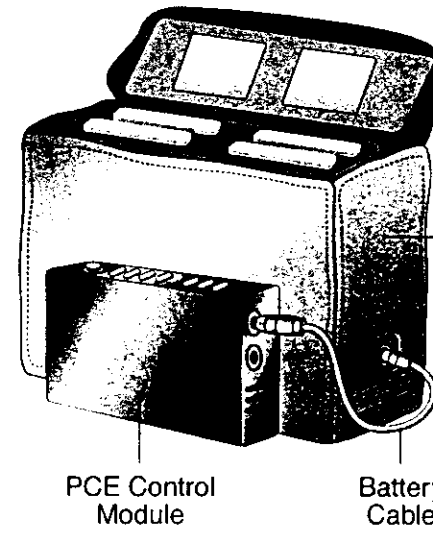

Figure 5.2 Plugging the Battery Cable into the Control Module

3 When the PCE TET alarm sounds, press the Silence Alarm button on the PCE Control Module (Figure 5.3)

The TET alarm light will turn red; this is normal.

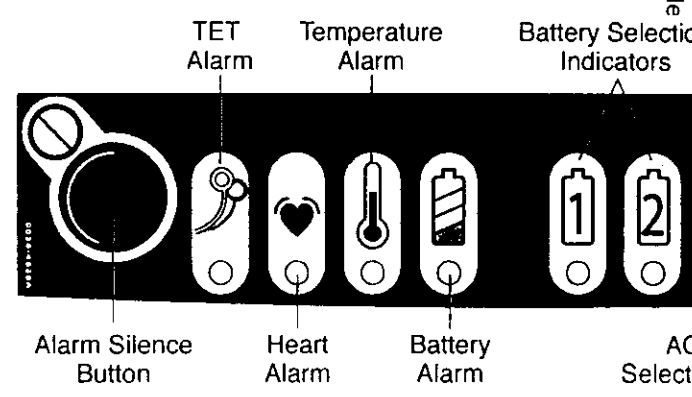

Figure 5.3 Silencing the TET Alarm

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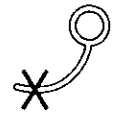

Figure 5.4 Console TET Unplugged

Figure 5.5 Silencing Console Alarms

Unplug the TET from the Console.

- Do not remove the TET or the DuoDerm patch fr your chest.
- The "TET Unplugged" symbol appears on the C screen (Figure 5.4) and the TET alarm sounds. T normal.

Press the Console alarm silence button (Figure 5.5

5 Plug the TET connector into the PCE Control Module as shown in Figure 5.6.

The TET alarm light on the PCE Control Module will turn off.

WARNING: The TET is now powered; keep it away from metal surfaces.

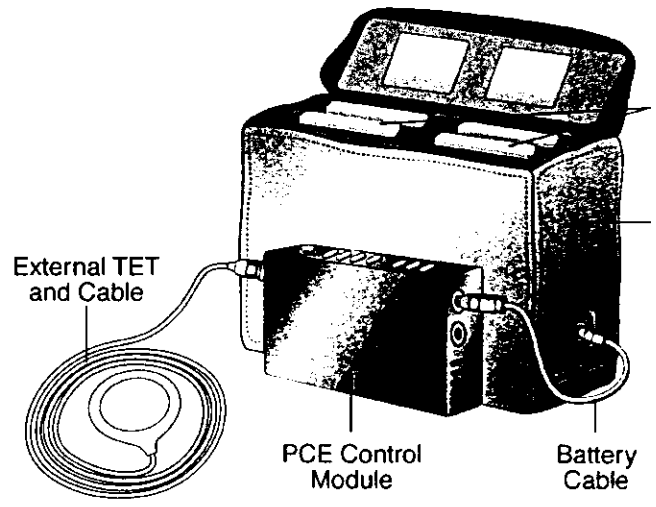

Figure 5.6 Connecting the TET to the PCE C Module

6

Figure 5.7 Console Power Panel After Transfer to PCE

Look at the Implanted Battery section of the Con Power Panel.

The Implanted Battery icon should be fully filled gray without a halo around it (Figure 5.7).

This tells you that the Implanted Battery is not th primary source of power for the Replacement He because the PCE is providing power.

7

Figure 5.8 Testing PCE Alarms

Figure 5.9 Checking the Heart Alarm Light

On the Console keypad, press the Test PCE alarm (Figure 5.8). The alarm panel displays the follow message:

Testing PCE alarm. You should now hear your F alarm buzzer. If you do not, call your Health Car Provider.

Be sure the Heart alarm light on the PCE Contro turns on (Figure 5.9) and the buzzer sounds.

If you do not hear the PCE alarm, move the RF Communications Module so it is near your abdor the Implanted Controller.

If the alarm does not sound, use a new PCE Cont Module.

If the alarm still does not sound, call your health provider.

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8

Figure 5.10 Putting the Console on Standby

Press the Console standby mode button (Figure 5.1(the Console into standby mode. This will quiet the (alarms. The Console display shows the following m

Enter standby mode? Only place the Console into s mode if no one is supported by it! Press the Consol standby button again to enter standby mode.

Press the standby mode button a second time to con that you want to put the Console on standby.

The Console display screen becomes black, with the standby icon showing in the corner, to tell you the C is in standby mode.

Transferring to the PCE if You Use a Different TET

If you want to change TETs when you transfer support to the PCE, follow this procedure.

1 Insert 2 pairs of fully-charged Batteries into slots in the Battery Bag as shown in Figure 5.11.

- Be sure that the Battery Pair in Place indicator lights between the Battery slots in the PCE Battery Bag (Figure 5.2) turn on when the Batteries are in place.
- If the indicator lights do not come on, be sure the Batteries are plugged securely into place.

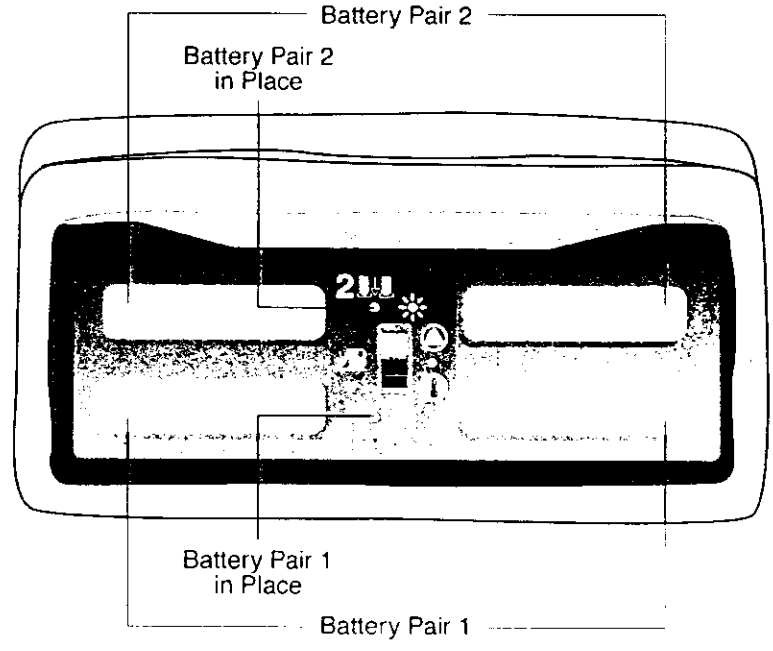

Figure 5.11 Installing Batteries in the Battery Bag

2 Plug the Battery Cable on the Battery Bag into the PCE Control Module as shown in Figure 5.12.

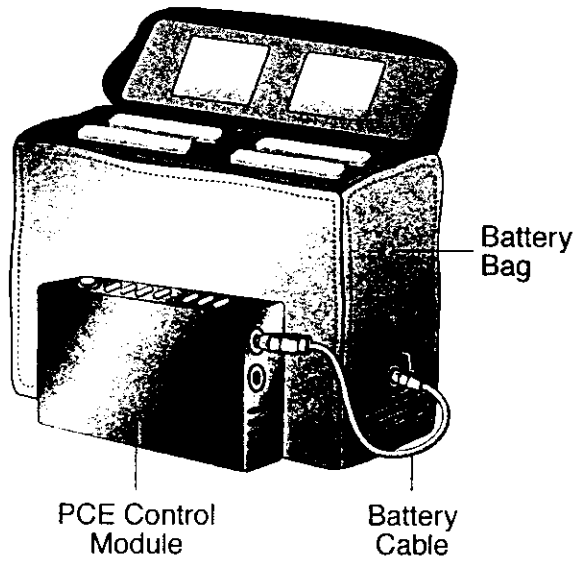

Figure 5.12 Plugging the Battery Cable into the PCE Control Module

3

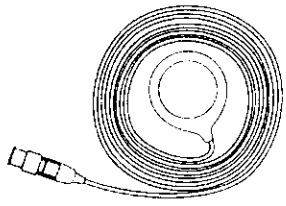

Figure 5.13 Removing the Console TET

Unplug the TET from the Console (Figure 5.13).

CAUTION: Be sure to keep the Console TET at least 1 foot away from the PCE TET.

Remove the TET from the DuoDerm Patch on your chest.

4

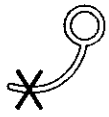

Figure 5.14 Console TET Unplugged

Figure 5.15 Silencing Console Alarms

The "TET Unplugged" symbol appears on the Console screen (Figure 5.14) and the Console TET alarm sounds. This is normal.

Press the Console alarm silence button (Figure 5.15).

Do the next steps within 2 minutes to minimize the amount of time that the Implanted Battery is discharging.

5 Plug the PCE TET connector into the PCE Control Module as shown in Figure 5.16.

The PCE TET alarm will sound; this is normal. Press the PCE alarm silence button (Figure 5.17, below) to quiet the alarm.

WARNING: The TET is now powered; be careful to keep it away from metal surfaces.

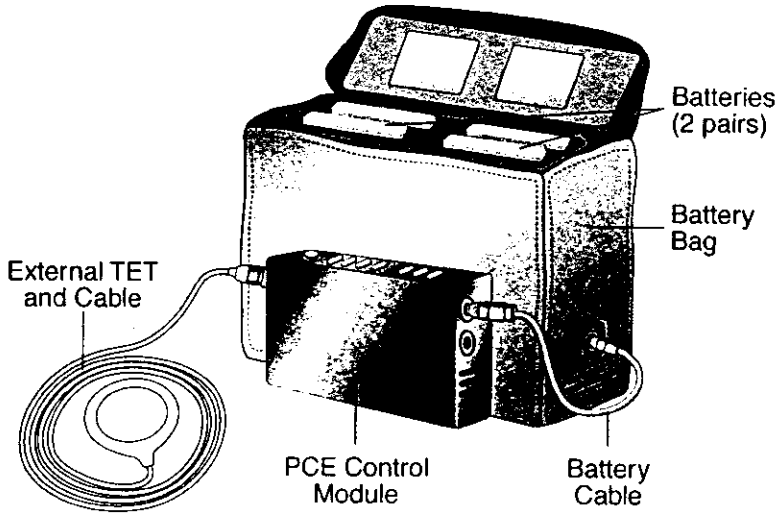

Figure 5.16 Connecting the TET to the PCE Control Module

6 Place the PCE TET on your chest.

Look at the TET alarm light on the PCE Control Module (Figure 5.17); when the light goes off, the TET is correctly aligned.

Secure the TET with the Velcro strips on the DuoDerm patch.

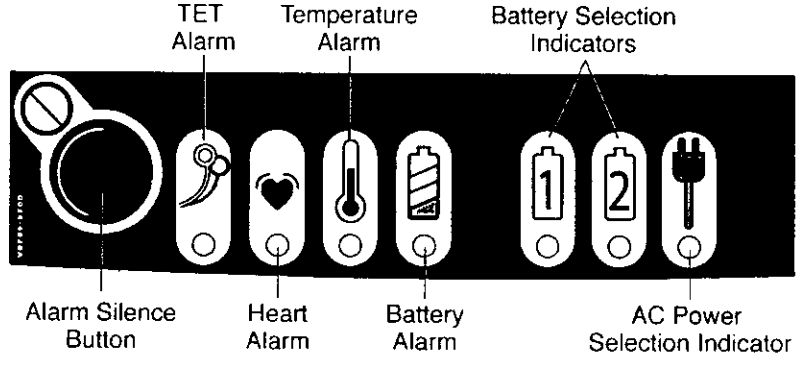

Figure 5.17 Silencing the PCE TET Alarm

7

Figure 5.18 Checking the Console Power Panel

Look at the Implanted Battery section of the Console Power Panel.

The Implanted Battery icon should be fully filled in with gray without a halo around it (Figure 5.18).

This tells you that the Implanted Battery is not the primary source of power for the Replacement Heart because the PCE is providing power.

8

Figure 5.19 Testing PCE Alarms

On the Console keypad, press the Test PCE alarm button (Figure 5.19). The alarm panel displays the following message:

Testing PCE alarm. You should now hear your PCE alarm buzzer. If you do not, call your Health Care Provider.

Be sure the Heart alarm light on the PCE Control Module turns on (Figure 5.20) and the buzzer sounds.

Figure 5.20 Checking the Heart Alarm Light

If you do not hear the PCE alarm, move the RF Communications Module so it is near your abdomen over the Implanted Controller.

If the alarm still does not sound, use a new PCE Control Module.

If the alarm still does not sound, call your health care provider.

9

Figure 5.21 Putting the Console on Standby

Press the Console standby mode button (Figure 5.21) to put the Console into standby mode. This will quiet the Console alarms. The Console display shows the following message:

Enter standby mode? Only place the Console into standby mode if no one is supported by it! Press the Console standby button again to enter standby mode.

Press the standby mode button a second time to confirm that you want to put the Console on standby.

The Console display screen becomes black, with the standby icon showing in the corner. to tell you the Console is in standby mode.

Transferring Support from the PCE to the Console

When you want to use the Console instead of the PCE, follow the step-by-step procedures listed below.

There are two different procedures:

- one procedure for using the same TET on the Console as you used on the PCE
- another procedure for changing TETs when you transfer support to the Console.

Transferring to the Console if You Use the Same TET

If you want to use the same TET with the Console as with the PCE, follow this procedure.

1

Figure 5.22 Bringing the Console out of Standby

Press the standby button on the Console (Figure 5.22) to bring the Console out of standby mode.

If Console alarms sound, use the Alarm Silence button (Figure 5.23) to quiet them.

Figure 5.23 Silencing Console Alarms

2

Plug the RF Communications Module into the Console, if it is not already connected.

Position the RF Communications Module to get a good RF communications signal.

Open the RF panel on the Console. Look for green arcs to show that the RF signal is strong in both directions (Figure 5.24). If the signal is not strong, move the RF Communications Module to improve the signal.

Do the next step within 2 minutes to minimize the amount of time that the Implanted Battery is discharging.

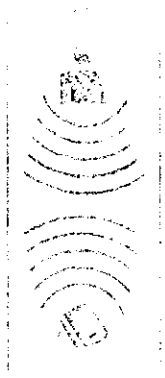

Figure 5.24 Checking the RF Communications Signal

3

Unplug the TET from the PCE Control Module.

The PCE TET alarm will light and the buzzer will sound. Press the alarm silence button to quiet the alarm (Figure 5.25).

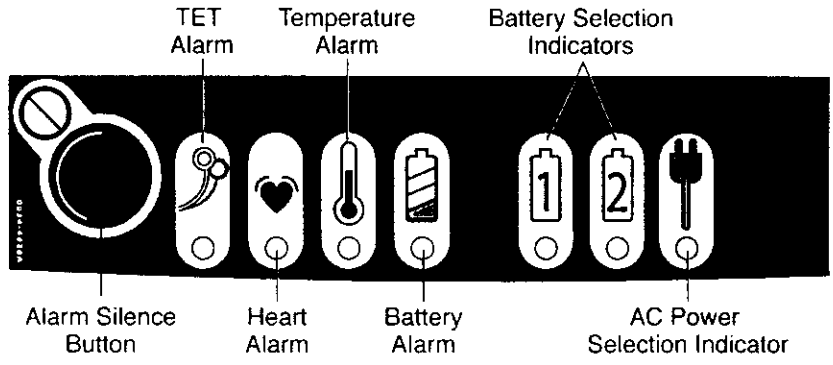

Figure 5.25 Silencing the PCE TET Alarm

4 Plug the TET into the Console TET connector (Figure 5.26)

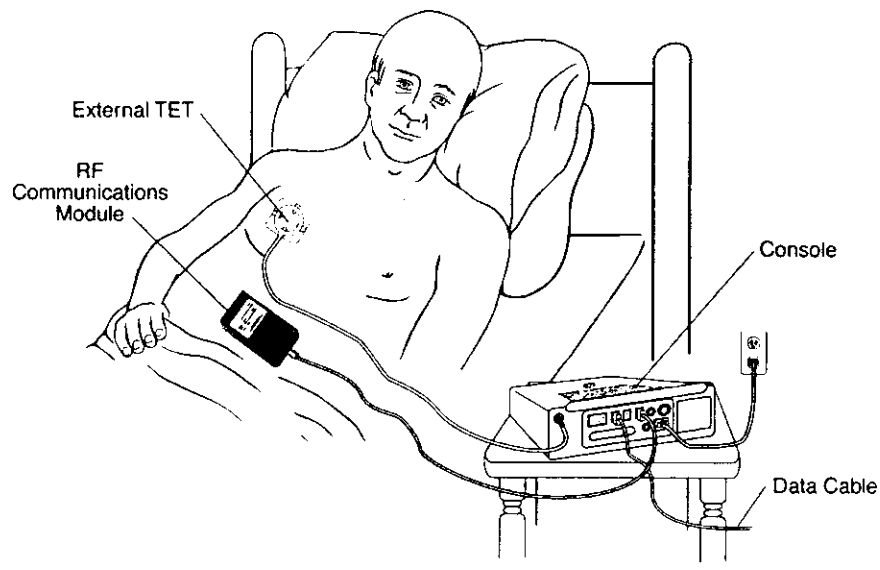

Figure 5.26 Connecting the TET to the Console

5

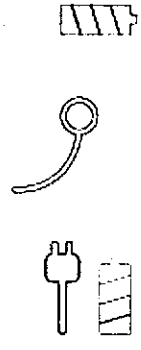

Figure 5.27 Checking TET Alignment and Power on Console Power Panel

Open the Power panel. Using Figure 5.27 as a reference,

- Be sure the TET is aligned correctly (a green TET in the center section of the panel)
- Be sure the system is receiving power from the Console (there is no halo around the Implanted Battery icon).

6 Open the top cover of the PCE Battery Bag (Figure 5.28).

Remove the PCE Batteries.

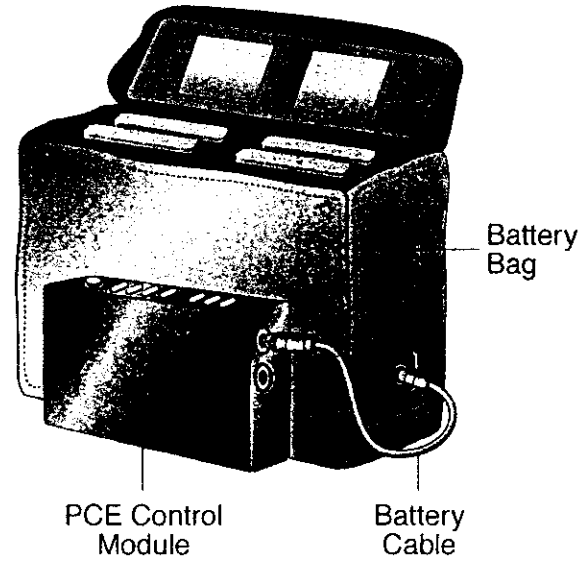

Figure 5.28 Removing the PCE Batteries from the Battery Bag

7 Be sure the Battery Charger is plugged in.

Place the PCE Batteries in the Battery Charger (Figure 5.29).

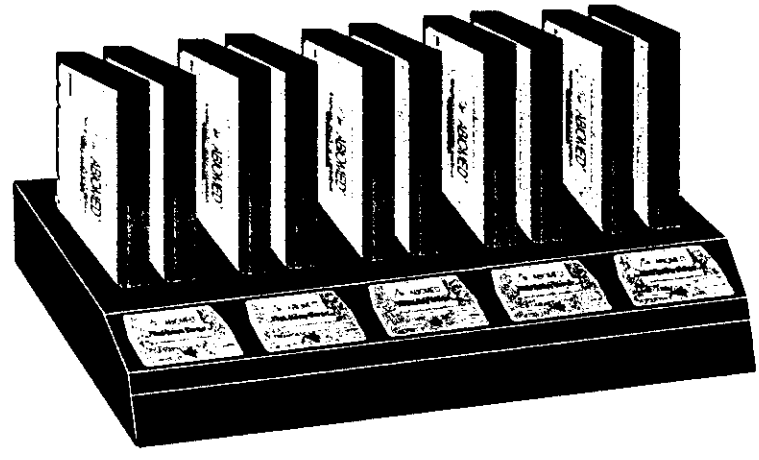

Figure 5.29 Charging the Used Batteries

Transferring to the Console if You Use a Different TET

To transfer support from the PCE to the Console, if you want to use a different TET with the Console, follow this procedure.

CAUTION: Keep a TET that is connected to the Console at least 1 foot away from any other TET (for example, the PCE TET.)

This precaution prevents potential damage to the TET's electronics.

CAUTION: Never place a powered TET on a metal surface.

The TET may become overheated, resulting in a fire hazard.

1

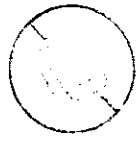

Figure 5.30
Bringing the Console out of Standby

Press the standby button on the Console (Figure 5.30) to bring the Console out of standby mode.

2

Figure 5.31
Checking the RF Communications Signal

Plug the RF Communications Module into the Console, if it is not already connected.

Position the RF Communications Module to get a good RF communications signal.

Open the RF panel on the Console. Look for green arcs to show that the RF signal is strong in both directions (Figure 5.31). If the signal is not strong, move the RF Communications Module to improve the signal.

Do the next step within 2 minutes to minimize the amount of time that the Implanted Battery is discharging.

3 Remove the PCE TET from your chest. Do not remove the DuoDerm patch.

Do not unplug the TET from the PCE Control Module yet.

4 Place the Console TET on your chest.

Secure it with the Velcro strips on the DuoDerm patch.

5 Unplug the TET from the PCE Control Module.

The PCE TET alarm will light and the buzzer will sound. Press the alarm silence button to quiet the alarm (Figure 5.32).

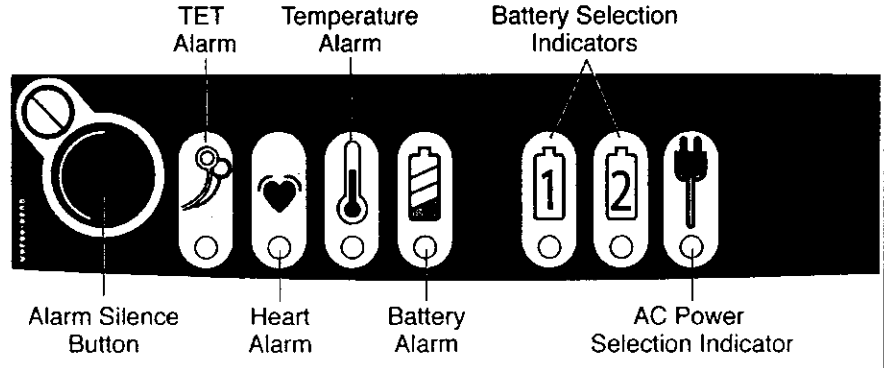

Figure 5.32 Silencing the PCE TET Alarm

6 Plug the Console TET into the Console TET connector (Figure 5.33)

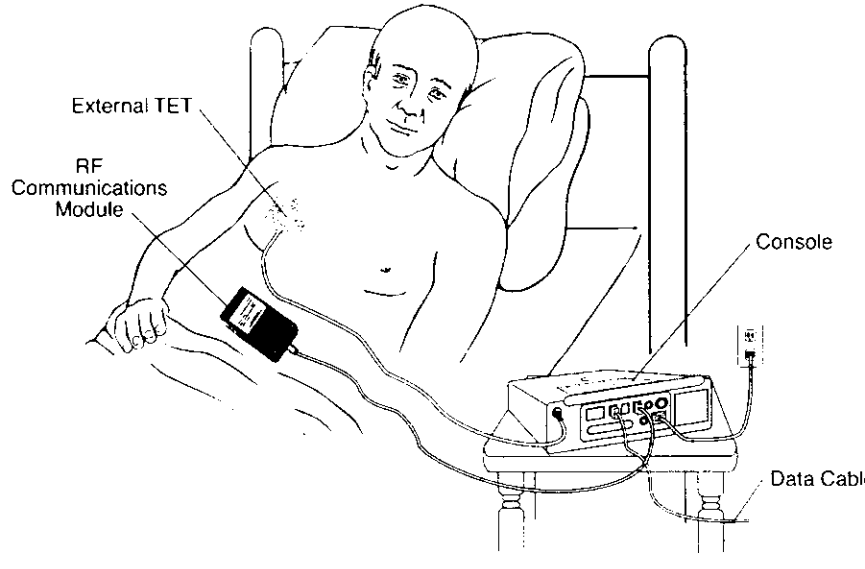

Figure 5.33 Connecting the TET to the Console

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7 Open the Power panel. Using Figure 5.34 as a reference:

- Be sure the TET is aligned correctly (a green TET in the center section of the panel) Reposition the TET on your chest if the TET is not correctly aligned.
- Be sure the system is receiving power from the Console (there is no halo around the Implanted Battery icon).

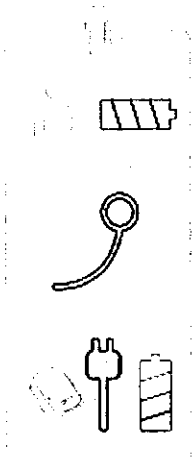

Figure 5.34 Checking TET Alignment and Power on Console Power Panel

8 Open the top cover of the PCE Battery Bag (Figure 5.35).

Remove the PCE Batteries.

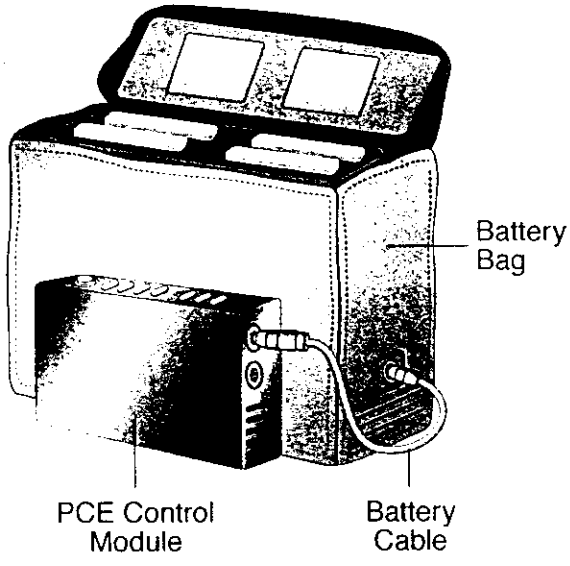

Figure 5.35 Removing the PCE Batteries from the Battery Bag

9 Be sure the Battery Charger is plugged in.

Place the PCE Batteries in the Battery Charger (Figure 5.36).

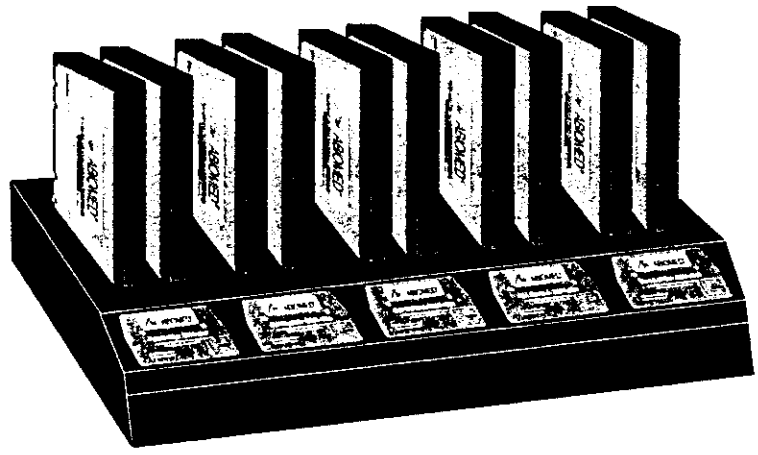

Figure 5.36 Charging the Used Batteries

6 Alarms

The AbioCor System constantly monitors itself to be sure everything is running smoothly. If the system discovers that something isn't working correctly, it sends out an alarm.

You can see these alarms on the Console display screen. You can also hear them, to be sure that you notice the alarm condition as quickly as possible.

The Alarm panel

The Alarm panel, at the top of the Home Screen, displays text to tell you about any alarm condition that occurs.

- RED alarms are warnings about life-threatening problems.
- YELLOW alarms are caution messages about serious problems.
- WHITE alarms are information alerts.

The alarm text stays on the screen until the alarm is cleared by fixing the problem that caused the alarm.

Table 6.1 lists the alarms that you might see on the AbioCor Console alarm display. The Console display tells you what to do for each alarm condition.

Note: Pay attention to the alarms and check them as soon as they occur; some alarms warn you about conditions that could be life-threatening.

Table 6.1 Alarms Overview

Alarm Color	Alarm Message on Screen
Red (Life-threatening problems)	Implanted battery critically low TET fault or misalignment Low flow Low flow: left heart pressure low Low flow: heart pressure low
Yellow (Serious problems)	Heart pressure low Left heart pressure low Implanted battery low Communications loss Console Battery critically low Console Battery low
White (information)	Network connection lost Implanted battery fault Console Battery fault

Panel pop-ups on the Console display

Some kinds of alarm conditions also cause a pop-up to appear on the Power panel. These pop-ups are explained in the Power panel discussion in Section 4 of this manual.

Alarm sounds

Alarms are also announced by sounds:

- Red alarms are announced by a continuous 2-tone message that sounds like, "eeee-oooo-eeee-oooo," repeated until the alarm is silenced or resolved.
- Flashing yellow alarms indicate a TET misalignment. This alarm sounds like oooooooo-ee-..., repeated until the alarm is silenced or resolved.
- Yellow alarms sound like ee-ee-ee-ee....ee-ee-ee-ee..., repeated until the alarm is silenced or resolved.
- White alarms (information alerts) sound like eeee-oo. A white alarm sounds only once; it does not repeat.

To quiet the alarm temporarily while you decide what you should do about it, press the alarm silence button on the Console keypad.

The alarm will be quieted for about 2 minutes.

If the alarm condition still exists after 2 minutes, or if a new alarm condition occurs, the alarm will sound again.

Appendix: Federal Communications Commission (FCC) Notice

AbioCor Components	Notice
AbioCor Console	This device complies with Part 18 of the FCC Rules.
PCE Control Module	This device complies with Part 18 of the FCC Rules.
RF Communication Module	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Handheld Monitor	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Implantable Controller	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.

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AbioCor®

Implantable Replacement Heart System

PATIENT-CARRIED ELECTRONICS MANUAL

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July 2004
Document No. 0034-0980-00016 Rev. 1

Humanitarian Device. Authorized by Federal law for use in the treatment of patients with irreparably damaged hearts, at imminent risk of death with no other treatment options. The effectiveness of this device for this use has not been demonstrated.

IMPORTANT NOTICE: Read this ***entire*** manual before using the Patient-Carried Electronics (PCE). The PCE is to be used only in accordance with this manual.

Information contained in this document is subject to change without notice.

Contents

Tables

Glossary

AbioCor Replacement Heart	battery-powered system that takes the place of the natural heart to keep the blood flowing normally through the body
alternating current (AC)	normal household electrical power
cardiopulmonary resuscitation (CPR)	first-aid technique that uses pressure against the chest to restore the operation of a natural heart
Console	specialized computer that powers and controls the AbioCor System
External Transcutaneous Energy Transmission coil (External TET)	silicone ring containing a coil of wire; transfers energy from the Console to the implanted components of the AbioCor System
heart rate	number of times per minute the Replacement Heart pumps blood
implanted	placed inside your body by a surgeon
Implanted Battery	AbioCor component that provides power to the Implanted Controller and the Replacement Heart
Implanted Controller	AbioCor component that manages the heart rate and stroke volume of the Replacement Heart to provide the needed blood flow
Implanted Transcutaneous Energy Transmission coil (Implanted TET)	AbioCor component that receives electrical energy through your skin from the External TET to keep your AbioCor System charged
magnetic resonance imaging (MRI)	diagnostic technique that produces images of the inside of the body using electromagnetic energy
Patient-Carried Electronics (PCE)	portable system that provides battery power to the implanted AbioCor System through an External TET

precaution	information that alerts you to situations that carry a risk of minor injury to you, or situations in which the AbioCor Replacement Heart may malfunction or be damaged
Replacement Heart	the AbioCor component that is implanted in your chest to pump blood to your lungs and other parts of your body
RF	radio frequency; the type of communications signal used by the AbioCor System
RF Communications Module	external AbioCor component that sends data between the Console and the AbioCor Implanted Controller through the implanted RF Antenna
TET	transcutaneous energy transmission; transfers power from the Console to the implanted AbioCor System
warning	information that alerts you to situations that can cause death or serious injury

Introduction

The **AbioCor Replacement Heart** is a battery-powered system for patients with heart failure or another serious heart disease. It takes the place of your natural heart to keep the blood flowing normally through your body.

The **Patient-Carried Electronics (PCE)** is a portable system that provides power to the implanted AbioCor System while you are away from the AbioCor Console.

About this Manual

This manual will help you understand how to use the PCE safely and comfortably.

Manual Overview

After you read this introduction, take a moment to browse through this manual, so you'll know where to find the information you need.

- **Section 1 (Warnings and Precautions)** lists important precautions to avoid potential safety problems and ensure that you get the best results from your AbioCor System.
- **Section 2 (PCE Overview)** describes the parts of the Patient-Carried Electronics (PCE).
- **Section 3 (Basic PCE Operation)** tells how to use the PCE and how to charge, replace, and calibrate Batteries. It also tells how to clean the system.

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- **Section 4 (Transferring Support Between the Console and PCE)** tells how to transfer support from the AbioCor Console to the PCE when you want to be away from the Console and how to transfer support from the PCE back to the Console.

- **Section 5 (PCE Alarms)** describes the alarms you might see and hear when you are using the PCE.

Definitions of Special Terms

This manual may use words that are new to you. Those terms are printed in bold type **(like this)** and listed in alphabetical order in the Glossary at the front of this manual. The Glossary also includes abbreviations used in this manual.

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1 Warnings and Precautions

This section contains two kinds of information.

- **Warnings** alert you to situations that can cause death or serious injury. The word "WARNING" and the symbol ⚠ appear before warning messages.
- **Precautions** alert you to situations that carry a risk of minor injury to you, or situations in which the AbioCor Replacement Heart may malfunction or be damaged. The word "CAUTION" and the symbol ⚠ appear before precaution messages.

AbioCor System Warnings

⚠ **WARNING:** Call your doctor or clinic immediately if the AbioCor System Console stops working.

If the Console stops working, connect the Patient-Carried Electronics (PCE) to provide power immediately.

The AbioCor Replacement Heart will work for only about 30 minutes using its Implanted Battery power. After that, your AbioCor Replacement Heart must be connected to the Console or PCE for power. Otherwise, it will stop working, resulting in death.

⚠ **WARNING:** If the External TET is removed, the AbioCor System runs on its Implanted Battery power, which only lasts for about 30 minutes.

When the Implanted Battery runs down, the AbioCor System will slow down, lowering your blood pressure. This might make you feel dizzy or faint. If the Implanted Battery runs down completely, the AbioCor System will stop working, resulting in death.

WARNING: Never undergo a **magnetic resonance imaging (MRI)** procedure.

The strong magnetic energy produced by an MRI machine may cause the AbioCor System components to give you an electric shock. An MRI may also damage the AbioCor System's electronics.

WARNING: Never administer **cardiopulmonary resuscitation (CPR)** to a person who has an AbioCor Replacement Heart.

CPR will not work with an AbioCor Replacement Heart, and may cause life-threatening bleeding.

WARNING: Never travel to an altitude that is more than 2,500 feet higher or lower than the location at which the AbioCor Replacement Heart was implanted.

If emergency air transportation is needed, tell the pilot about the 2,500-foot restriction.

Changes in air pressure caused by altitude changes may cause the AbioCor Replacement Heart to work incorrectly, resulting in death or serious injury.

WARNING: Do not allow any metal objects within 3 inches of the External TET while it is powered. Certain types of metal objects may quickly become extremely hot and present a burn or fire hazard.

WARNING: If you have an X-ray, the technician may put a lead shielding apron over your chest.

Put a thick pad (a Styrofoam® block or a folded towel at least 3 inches thick) between the AbioCor TET and the lead shielding apron, or remove the TET for a short time during the X-ray.

Without a thick pad, the AbioCor System components may get hot during the X-ray, causing a risk of a skin burn.

Patient-Carried Electronics (PCE) Warnings

WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE Battery Bag and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

WARNING: If the PCE Temperature alarm stays on for more than 1 minute, transfer AbioCor System control immediately to a backup PCE or the Console.

This warning indicates that the PCE is overheated and may malfunction.

AbioCor System Precautions

CAUTION: Do not bend forward deeply from the waist. This posture might be uncomfortable because of the location of the Implanted Battery and Implanted Controller in your abdomen.

Bending forward may also affect the blood flow to your upper body, which may cause a momentary fainting spell.

CAUTION: Do not clean the External TET, Radiofrequency (RF) Communications Module, or cables with disinfectants that contain oxidizers such as iodine (Betadine® or similar disinfectants), hydrogen peroxide, hypochlorite (chlorine bleach), permanganate, or chromate.

These cleaners may break down the outer coverings of these AbioCor components.

CAUTION: Do not clean the External TET, RF Communications Module, or cables with cleaners that may stain the surfaces you are cleaning.

This staining may hide the breakdown of the outer coverings of these AbioCor components.

CAUTION: Do not allow any liquids (including water) to come in contact with any electrical connector pins.

Contact with liquid may cause corrosion or electrical malfunction.

CAUTION: Keep a TET that is connected to the Console at least 1 foot away from any other TET (for example, the PCE TET.)

This precaution prevents potential damage to the TET's electronics.

CAUTION: Never place a TET that is connected to the PCE or Con metal surface.

The TET may become overheated, causing a fire hazard.

CAUTION: Disconnect the TET from the Console when it is not in use (for example, when you are using the PCE.)

This precaution reduces the risk that the TET will be damaged by accidentally coming in contact with metal surfaces.

CAUTION: Keep the Console away from sources of electromagnetic radiation (EMR) such as cell phones, 2-way radios, or appliances with electric motors if you observe signs of interference (for example, static on the phone or radio or on the AbioCor Console screen).

These devices may interfere with the AbioCor's communications system.

Patient-Carried Electronics (PCE) Precautions

CAUTION: Never try to disassemble the PCE Control Module, Battery Bag, or Batteries.

You may damage the PCE and cause it to operate incorrectly.

CAUTION: Always have 2 power sources connected to the PCE to ensure that you will be able to see and hear alarms if they occur. These power sources can be:

- 2 pairs of Batteries
- 1 pair of Batteries and an AC Power Adapter.

CAUTION: Never cover the PCE with clothing.

Covering the PCE may cause it to overheat and operate incorrectly.

CAUTION: Never block the PCE's cooling vents.

Blocking the cooling vents may cause the PCE to overheat and operate incorrectly.

CAUTION: Never use a PCE Battery that has been dropped. It may not work correctly.

If you drop a PCE Battery, mark it DO NOT USE and return it to your doctor or clinic.

CAUTION: Never submerge any part of the PCE in liquid.

Liquids will severely damage the PCE and cause it to operate incorrectly.

2 PCE Overview

What is the Patient-Carried Electronics (PCE)?

The Patient-Carried Electronics (PCE) is a portable system that provides battery power to the implanted AbioCor System through the **External TET**. The PCE is carried in a nylon Battery Bag that you can wear over your shoulder. The PCE allows you to be mobile, away from the Console, for extended periods of time.

Like the **Console**, the PCE monitors your AbioCor System, using lights and sounds to tell you if there is a problem with the system.

Figure 2.1 shows how the PCE is used.

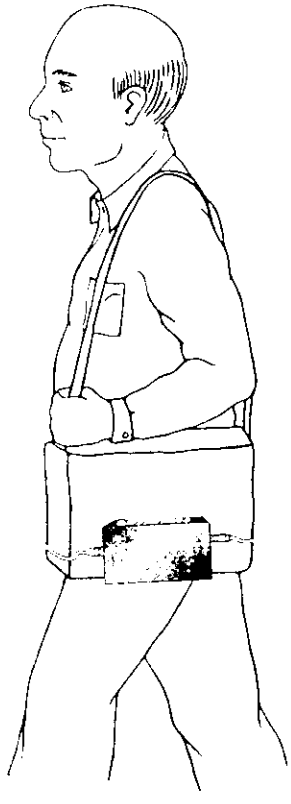

Figure 2.1 Using the PCE

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Parts of the PCE

The PCE includes the following parts, which are shown in Figures 2.2, 2.3, and 2.4.

- Battery Bag
- Batteries (2 pairs)
- Battery cable
- External TET
- PCE Control Module
- Battery Charger
- AC Power Adapter
- Handheld Monitor (not shown; described in a separate manual)

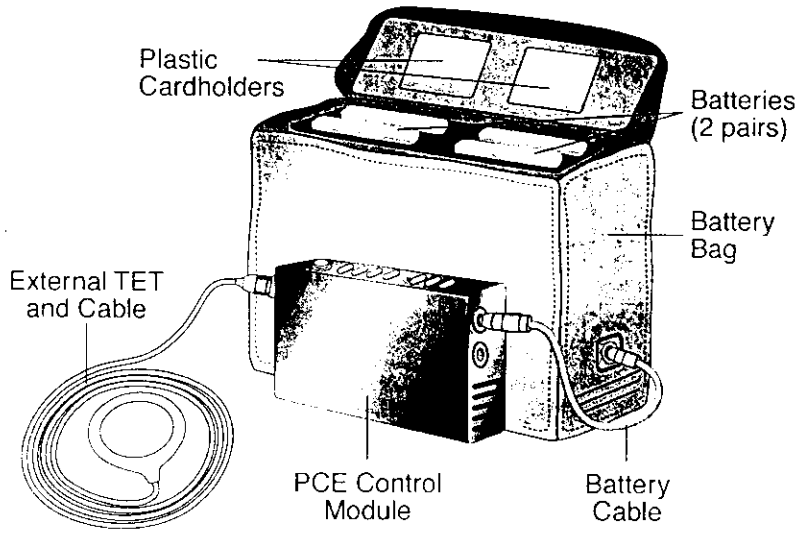


Figure 2.2 Parts of the PCE

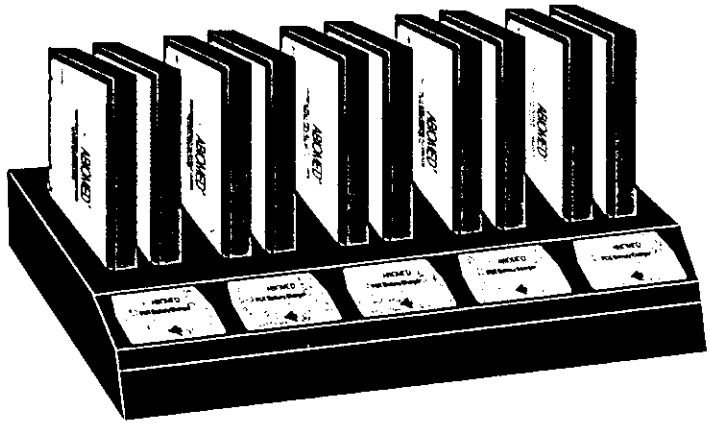


Figure 2.3 PCE Battery Charger

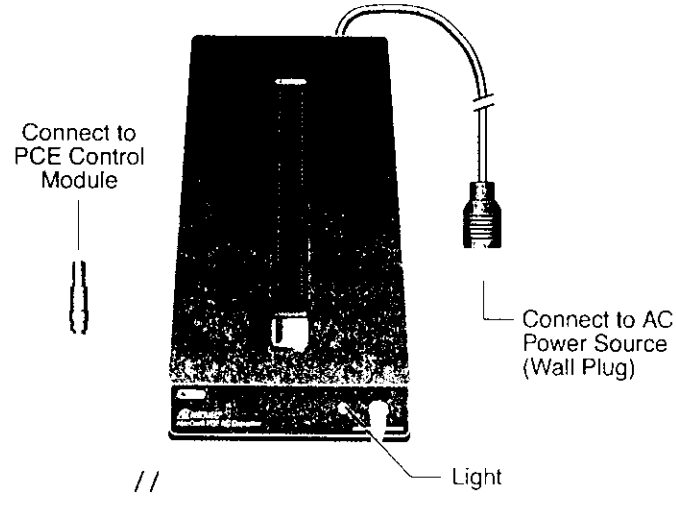


Figure 2.4 AC Power Adapter

PCE Battery Bag

The PCE Battery Bag holds 2 pairs of PCE Batteries and the Battery control electronics. The Battery Bag, which weighs about 10 pounds with the Batteries in place, has a shoulder strap so you can carry it easily. It has mesh pouches on the outside to hold the PCE Control Module, extra length of TET Cable, and other small items. Plastic cardholders inside the top cover can be used to keep emergency phone numbers close at hand.

CAUTION: Never cover the PCE with clothing.

Covering the PCE may cause the PCE to overheat and operate incorrectly.

CAUTION: Never block the PCE's cooling vents.

Blocking the cooling vents may cause the PCE to overheat and operate incorrectly.

Figure 2.5 shows the inside of the PCE Battery Bag with the zipper top opened.

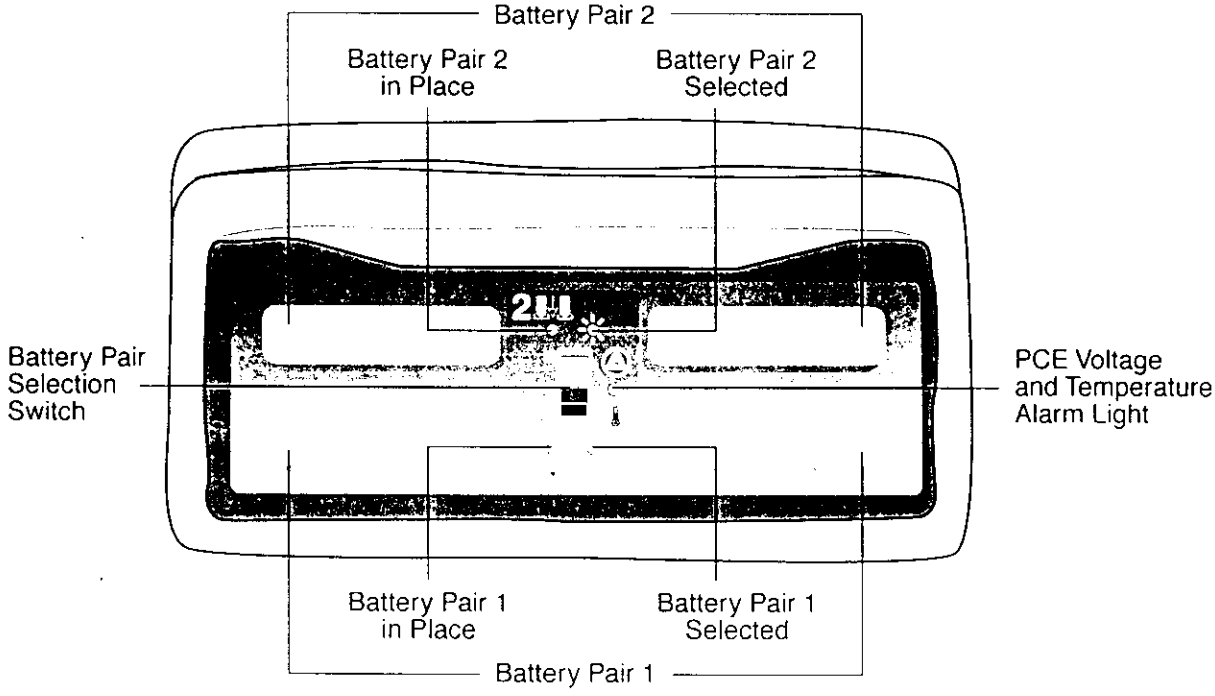


Figure 2.5 PCE Battery Bag with Batteries Installed

The functions of the Battery Bag switch and indicators are explained in Section 3 of this manual.

PCE Batteries

The PCE holds 2 pairs of Batteries—a total of 4 Batteries.

Each pair of Batteries provides power for the AbioCor's implanted components for about one hour. After that, you should switch to another set of Batteries and charge the used ones.

Information later in this manual tells you how to replace and recharge the Batteries.

Store Batteries in a dry location, out of direct sunlight, that does not exceed 100° F.

Batteries must be used in matched pairs

Batteries operate in matched pairs, and they must always be used together.

You can tell which Batteries go together in 2 ways:

- the number on the top edge of the Battery; both Batteries in a pair have the same number
- the serial number on the flat side of each Battery; both Batteries in a pair have the same serial number, except that one ends in A and the other ends in B. For example, one pair of Batteries may have the serial numbers 003000A and 003000B.

Figure 2.6 shows the serial number on the side of the Battery.

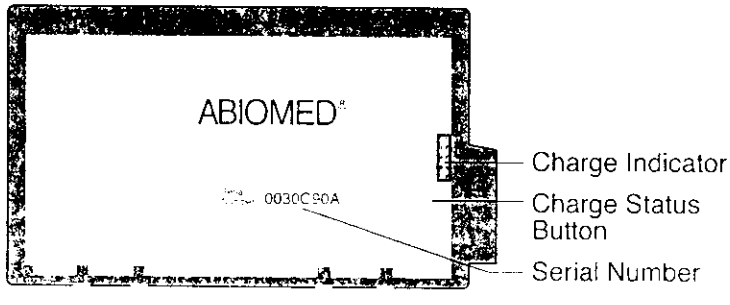


Figure 2.6 PCE Battery

Battery charge status

You can see whether a Battery is charged by checking the charge indicator on the flat side of the Battery, near the serial number (Figure 2.6). Press the Charge Status button below the Charge Indicator. If all 4 indicator lights do not turn on, the Battery needs to be charged.

If the charge on the pair of Batteries that you are using in the PCE is low, the Battery status alarm on the PCE Control Module will light. When this happens, switch to the other pair of Batteries right away.

You use the Battery charger to recharge the Batteries. Refer to "Charging Batteries" in Section 3 of this manual.

CAUTION: Never use a PCE Battery that has been dropped. It may not work correctly.

If you drop a PCE Battery, mark it DO NOT USE and return it to your doctor or clinic.

Battery Cable

The Battery Cable connects the PCE Control Module to the PCE Battery Bag. One end of the Battery Cable is permanently connected to the Battery Bag; the other end plugs into the PCE Control Module (in either the top or bottom socket).

To unplug the Battery Cable from the PCE Control Module, hold the connector with your fingers on the wide part of the connector sleeve. Pull back the connector sleeve. Do not pull on the cord.

To plug the Battery Cable into the PCE Control Module, line up the arrows and push the connector sleeve towards the PCE Control Module. (You can also determine if the orientation is correct by rotating the connector until the key slot engages.)

External TET

The External TET plugs into the PCE Control Module as shown in Figure 2.7. You can use the same 5-foot or 11-foot TETs with the PCE as you use with the Console. Cover the TET connector with the cap provided when the TET is not in use.

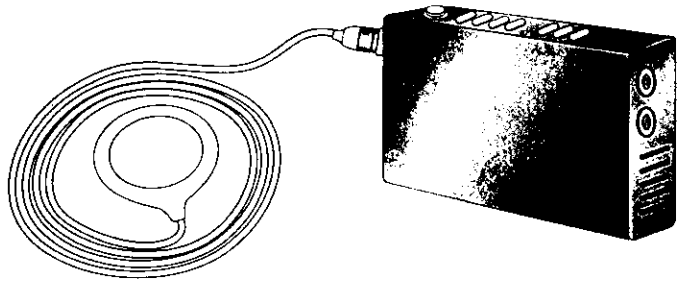


Figure 2.7 PCE Control Module with TET

PCE Control Module

The PCE Control Module (Figure 2.7) is a separate unit that is connected to the Battery Bag by the Battery Cable. It can also be connected directly to AC Power through the AC Power Adapter. The PCE Control Module does two main things:

- It converts Battery energy or DC power from the AC Power Adapter into energy that can be transmitted to the AbioCor System's implanted parts through the TET.
- It notifies you about alarms for the PCE or for any of the AbioCor System's implanted parts.

  Refer to Section 5 of this manual for more information about the PCE Alarms.

The functions of the PCE Control Module are explained in Section 3 of this manual.

Battery Charger

The Battery Charger holds 5 pairs of Batteries, so you can always have enough fresh Batteries available. It plugs into a standard AC electrical power plug.

Normal charge time is 6 hours. You can charge Batteries in 3 hours, however, by using only the left-hand slot of each 2-bay unit of the Charger. This works because each pair of Batteries is charged one at a time, starting with the left side of the charging unit bay.

Always keep your Battery Charger plugged in, and keep any Batteries that are not in your PCE charged so they are ready when you need them.

Figure 2.8 shows the Battery Charger.

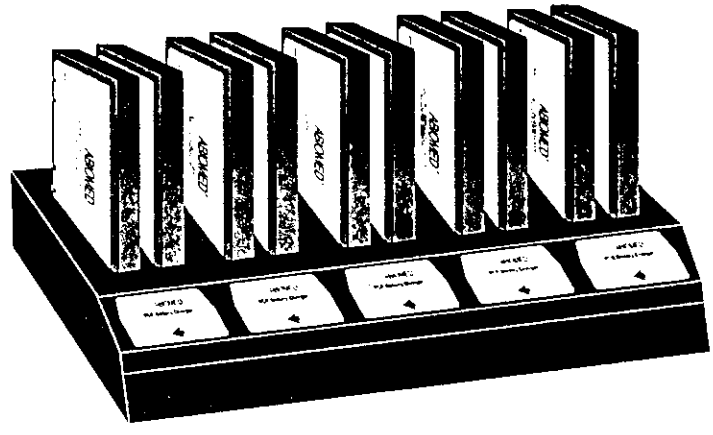


Figure 2.8 PCE Battery Charger

AC Power Adapter

If you are going to be away from the Console, but in a place where standard AC power is available (for example, at home or at a friend's house), you can connect your PCE Control Module to standard AC power using the AC Power Adapter. This ensures a steady source of power to the PCE while saving Batteries.

CAUTION: Always have 2 power sources connected to the PCE to ensure that you will be able to see and hear alarms if they occur. These power sources can be:

- 2 pairs of Batteries
- 1 pair of Batteries and an AC Power Adapter

The PCE's AC Power Adapter has 2 power cords:

- One connects the Adapter to an AC power source (wall plug)
- The other connects the Adapter to the PCE Control Module (in either the upper or lower socket).

The light on the front of the AC Power Adapter shows when it is plugged into AC power. Figure 2.9 shows the AC Power Adapter.

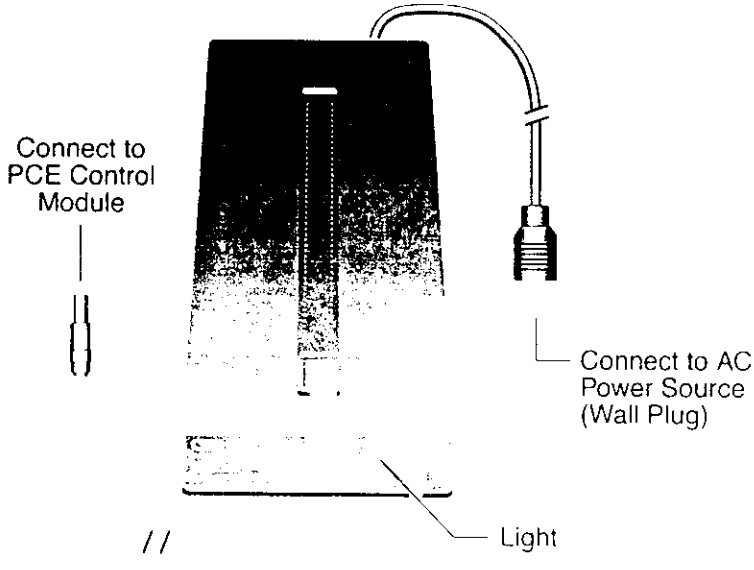


Figure 2.9 AC Power Adapter for the PCE

The AC Power Adapter has vents and a cooling fan inside. Keep the vents uncovered to ensure that the AC Power Adapter does not become overheated.

The AC Power Adapter also has a handle to make it easy for you to take it with you when you move about.

When the AC Power Adapter is being used, the AC Power selection indicator on the PCE Control Module is lighted.

3 Basic PCE Operation

WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If a PCE problem alarm condition persists for more than 1 minute, exchange the PCE for one of these backup units.

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

This section of the manual explains how to use the PCE.
Information includes:

- PCE Control Module functions
- Battery Bag switch and indicators
- charging batteries
- getting the PCE ready for use
- changing a pair of PCE batteries
- calibrating batteries
- connecting the AC Power Adapter
- cleaning the PCE

PCE Control Module Functions

Figure 3.1 shows the PCE Control Module's panel.

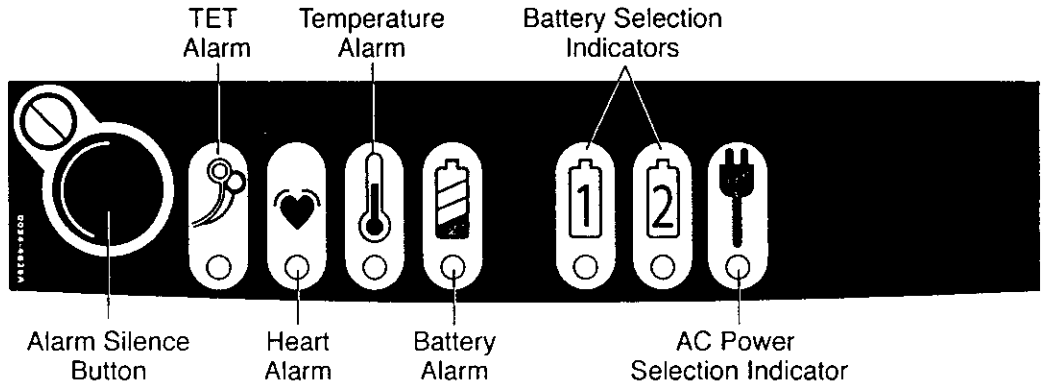


Figure 3.1 PCE Control Module Panel

Here is what the PCE Control Module panel button and lights are used for:

- **Alarm silence button**
  Press this push-button switch to temporarily turn off an audible alarm while you are resolving the cause of the alarm. If you are unable to resolve the alarm after 2 minutes, it will sound again.
- **TET alarm**
  The red light indicates that the PCE TET is out of alignment with the Implanted TET. Reposition the PCE TET; when the light turns green, alignment is OK.
- **Heart alarm**
  The light indicates that there is an alarm condition on the Implanted Replacement Heart, Implanted Controller, or Implanted Battery. Go to the Console or use the Handheld Monitor to find out what is wrong. If a setting needs to be changed, use the Console.
- **Temperature alarm**
  The light indicates that the temperature inside the PCE Control Module is too high.

Be sure that the PCE is in an open area, out of the sun, and that the cooling vents on the side of the Battery Bag are not covered by a coat or blocked by anything around them.

WARNING:

If a PCE temperature alarm condition persists for more than 1 minute, transfer control from the overheated PCE to a backup PCE or the Console.

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

- **Battery alarm**
  The light indicates that the charge on the selected pair of Batteries is low. Switch to the other pair of Batteries or connect the PCE's AC Power Adapter.

  Replace the low Batteries with freshly charged ones as soon as possible, so you always have spares ready.
- **Battery selection indicator**
  The light indicates which pair of Batteries is being used.

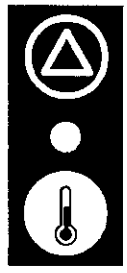
  Use the switch on the top of the PCE Battery Bag to select the other pair of Batteries.
- **AC power selection indicator**

  The light indicates that the PCE is using AC Power to operate.

Battery Bag Switch and Indicators

Table 3.1 tells what the switch and indicator lights on the PCE Battery Bag panel do.

Table 3.1 PCE Battery Bag Panel

Icon or picture and name		What it does
	Battery pair selection switch	Flip the switch to 1 or 2 to select the pair of Batteries to be used.
	Battery pair selection light	The light indicates which Battery pair is in use.
	Indicator light: Battery pair 1 in place	The light indicates that both Batteries in pair 1 are correctly seated in the PCE Battery Bag. This light *DOES NOT* indicate whether the batteries are charged.
	Indicator light: Battery pair 2 in place	The light indicates that both Batteries in pair 2 are correctly seated in the PCE Battery Bag. This light *DOES NOT* indicate whether the batteries are charged.
	PCE Voltage and Temperature Alarms	The light between the triangle icon and thermometer indicates a problem in the PCE Battery Bag. The light may be red or yellow. A RED light indicates a serious PCE Battery Bag power problem. Connect the AC Power Adapter right away. A YELLOW light indicates that the PCE has overheated. Be sure that the PCE is in an open area, out of the sun, and that the cooling vents on the side of the Battery Bag are not covered by clothing or blocked by anything around them.

Charging Batteries

Before you can use the PCE, you need to charge its Batteries.

PCE Batteries are used and charged in matched pairs. You should charge Batteries after any period of use to ensure that you always have enough fresh Batteries.

To see if a Battery needs to be charged, push the Charge Status button below the Charge Indicator on the Battery. (See Figure 3.2.) If less than 4 lights turn on, charge the Battery.

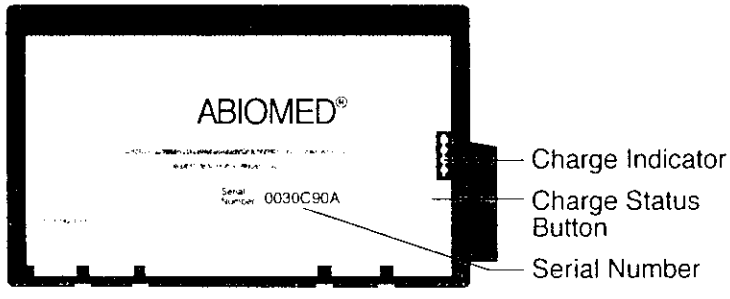


Figure 3.2 Location of the Battery Charge Indicator

To charge Batteries:

1. Plug the Charger's power cord into an AC outlet.
2. Insert the Batteries into the pairs of slots in the Battery Charger, with the connector edge down.
3. Confirm that the Charger's status lights turn on— one light for each bay. See Figure 3.3 for the location of the status lights (one light on each 2-Battery bay of the charger), and Table 3.2 for the meaning of the Status light conditions.
4. When the Batteries are fully charged, as indicated by solid green charging status lights, they are ready to use.

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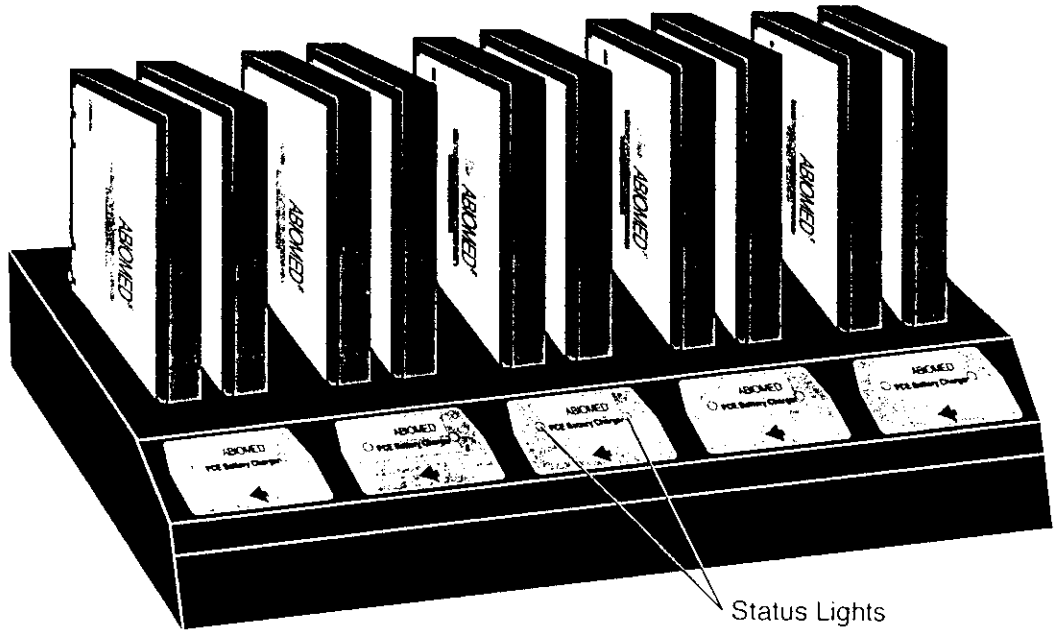

Figure 3.3 Battery Charger Status Lights

Table 3.2 explains the Charger status lights—what the different colors mean and what flashing means.

Table 3.2 Battery Charger Status Lights

Status Light Condition	What It Means
Off	No Battery, or Battery is not firmly seated in the charging bay.
Solid green	Battery is fully charged and ready to be removed.
Solid yellow	The bay of the charging unit is in Standby mode because the Battery in the other bay has not finished charging.
Flashing green	Battery is charging. Note: Each 2-bay charging unit charges 1 Battery at a time. The left bay is charged first.
Flashing yellow	The batteries are in the process of being recalibrated (discharged and recharged). Do not remove the batteries.
Flashing green and yellow	Battery recalibration is complete.
Flashing red	A failure has occurred during charging. Do not use the Battery. Mark the Battery, "Do Not Use" and return it to your Health Care Provider.

Getting the PCE Ready for Use

The PCE comes pre-assembled in the Battery Bag. To use the PCE for the first time, follow this procedure.

1. Install 2 matched pairs of freshly charged Batteries into the PCE Battery Bag. Confirm that the Batteries are seated correctly by checking the 2 "Battery pair in place" indicator lights on the Battery Bag, between the Batteries (Figure 3.4).

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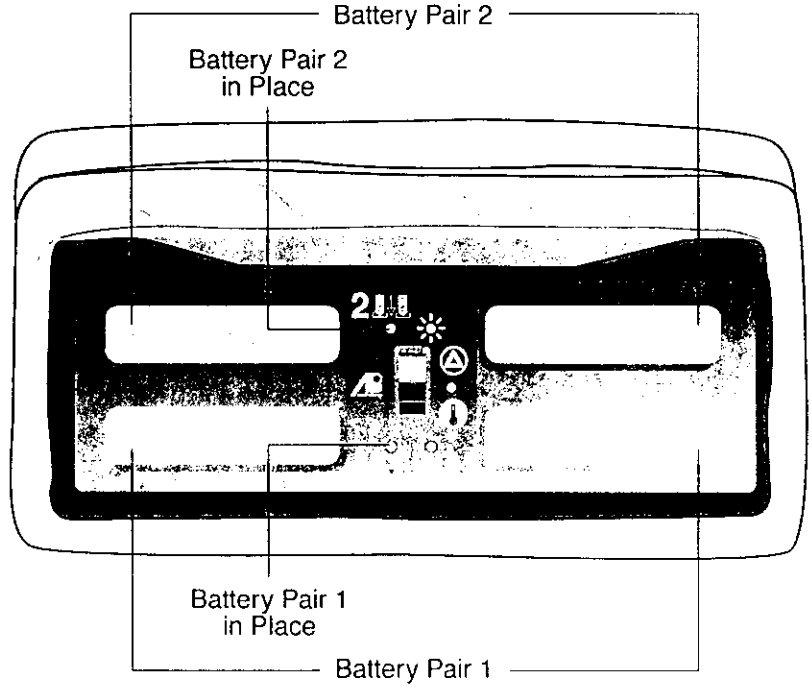

Figure 3.4 Installing the PCE Batteries

2. Plug the Battery Cable on the Battery Bag into the PCE Control Module as shown in Figure 3.5.

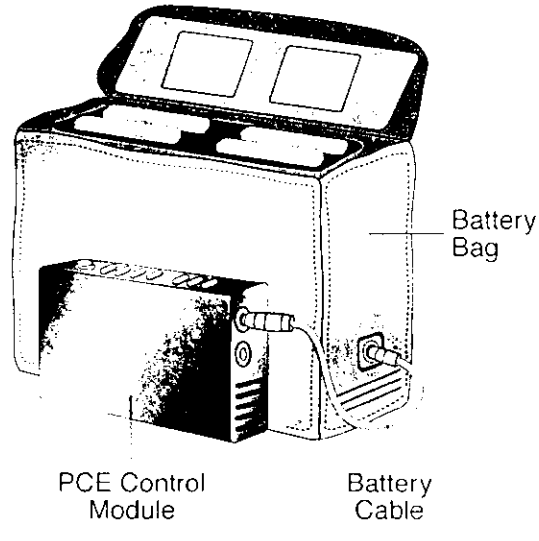

Figure 3.5 Plugging the Battery Cable into the PCE Control Module

3. Plug the TET into the PCE Control Module as shown in Figure 3.6.

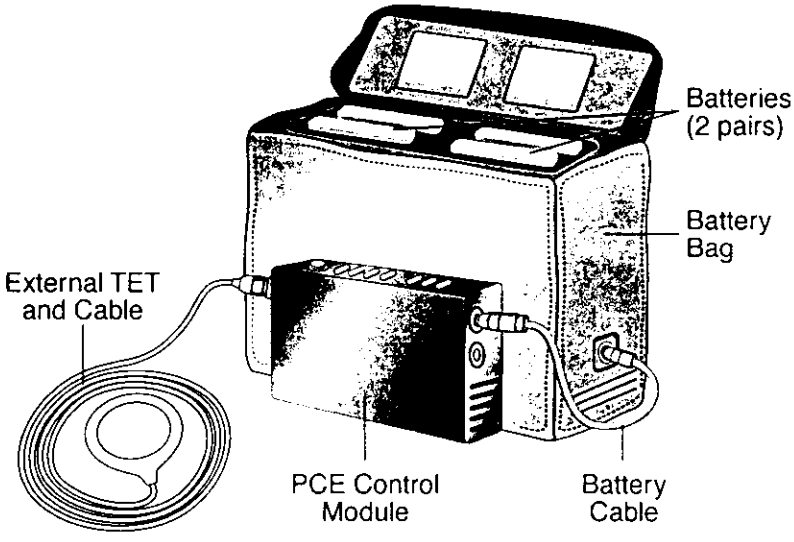

Figure 3.6 Plugging the TET into the PCE Control Module

4. Secure the PCE Control Module in the mesh pouch on the front of the Battery Bag (not shown) by closing the Velcro® fasteners.

CAUTION: Never place a TET that is connected to the PCE or Console on a metal surface.

The TET may become overheated, causing a fire hazard.

CAUTION: Keep a TET that is connected to the Console at least 1 foot away from any other TET (for example, the PCE TET).

This precaution prevents potential damage to the TET's electronics.

Changing a Pair of PCE Batteries

Change Batteries (in matched pairs) when either one of the following occurs:

- the PCE Battery alarm light is lit on the PCE Control Module
- the Batteries have been in use for 60 minutes

To change a pair of Batteries:

1. Open the top cover of the PCE Battery Bag (Figure 3.7).

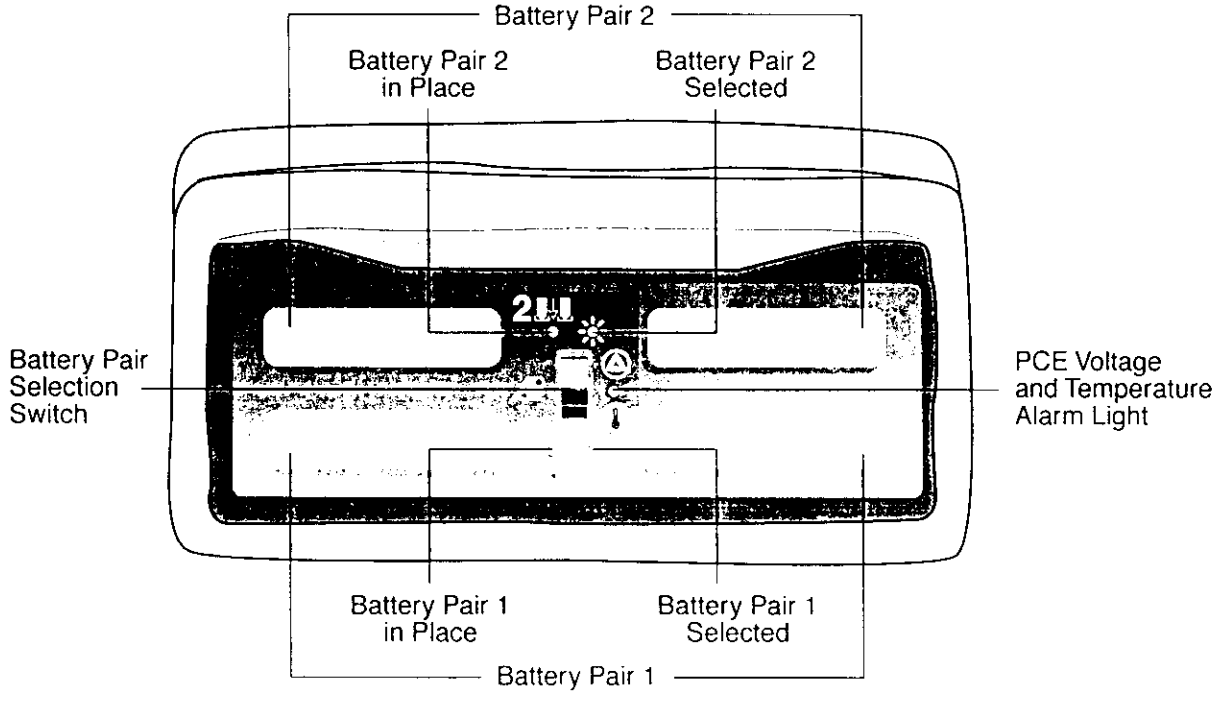

Figure 3.7 Changing Batteries

2. Flip the Battery Pair Selector switch in the PCE Battery Bag to the opposite position to select the other pair of Batteries. For example, if you were using Battery Pair 1, flip the switch to select Battery Pair 2.
3. Remove the used Batteries from the Battery Bag and place them in the Battery Charger. If the Charger is not available, set the Batteries aside for later charging.
4. Obtain a pair of freshly charged Batteries.
5. Confirm that the Batteries are a matched pair, by matching the numbers on the top ends of the Batteries and checking the serial numbers. The serial numbers should be the same, except that one should end in A and the other in B.
6. Insert the pair of Batteries into the PCE Battery Bag with the connector ends down. Confirm that the Batteries are seated correctly by checking the 2 Battery status lights on the Battery Bag panel between the Batteries (Figure 3.7).
7. Close the top cover of the Battery Bag.

Calibrating Batteries

To ensure that the Charge Indicator on each Battery is always accurate, all Batteries should be recalibrated (discharged and recharged) once a month.

To recalibrate PCE Batteries:

1. Plug the Battery Charger into an AC Power source (wall plug).
2. Insert one Battery in each of the five left-hand slots of the Battery Charger. (Leave the right-hand slots empty.)
3. Press the arrow on the front of *each* Battery Charger bay, where it says, "Press to recalibrate."
4. The Battery Charger fully discharges all the Batteries, resets their Charge Indicators to zero, and then charges the Batteries up again. The status lights on the front of the Battery Charger flash yellow during this time.
5. When the status light on the Battery Charger starts to blink yellow and green, the Battery calibration process is complete. Take the calibrated Batteries out of the Battery Charger.
6. Put five more Batteries into the left-hand slots and repeat the calibration process until all your Batteries are calibrated.

Connecting the AC Power Adapter

CAUTION: Always have 2 power sources connected to the PCE to ensure that you will be able to see and hear alarms if they occur.

If you are using the AC Power Adapter, have one pair of charged Batteries in place in the PCE.

To connect the AC Power Adapter (Figure 3.8):

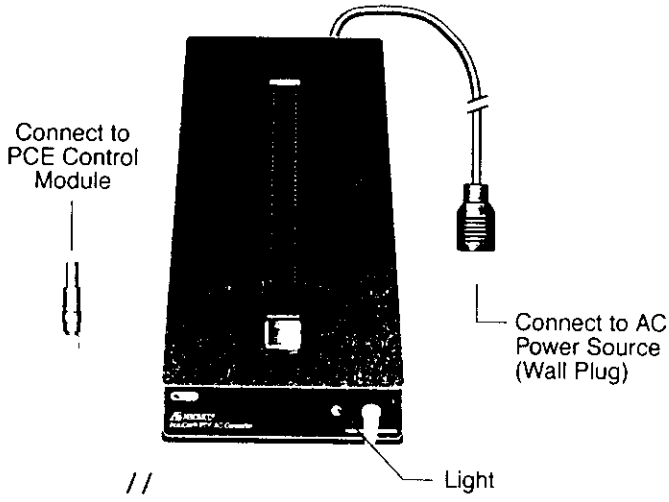

Figure 3.8 Connecting the AC Power Adapter

1. Plug the AC Power Adapter's power cord into an electrical outlet. Be sure the light on the AC Power Adapter is on to confirm that the power is on.
2. Plug the other Power Adapter cable into the unused Battery Cable socket on the outside of the PCE Control Module. (You can use either the top or bottom connector socket.)
3. Check the AC Power selection indicator on the PCE Control Module to be sure that AC Power is in use. If the light is not on, check the power connections.

Note: Using the AC Power Adapter does not recharge the Batteries that are in the PCE. They must be recharged in the Battery Charger.

Cleaning the PCE

CAUTION: Never submerge any part of the PCE in liquid.

Liquids will severely damage the PCE and cause it to operate incorrectly.

CAUTION: Do not allow any liquids (including water) to come in contact with any electrical connector pins.

Contact with liquid may cause corrosion or electrical malfunction.

CAUTION: Do not clean the TET, Radiofrequency (RF) Communications Module, or cables with disinfectants that contain oxidizers such as iodine (Betadine® or similar disinfectants), hydrogen peroxide, hypochlorite (chlorine bleach), permanganate, or chromate.

These cleaners may break down the outer coverings of these AbioCor components.

CAUTION: Do not clean the TET, RF Communications Module, or cables with cleaners that may stain the surfaces you are cleaning.

This staining may hide the breakdown of the outer coverings of these AbioCor components.

Cleaning the PCE Battery Bag and Control Module

1. Unplug the AC Power Adapter from the PCE, if it is connected.
2. Wipe the PCE Battery Bag and PCE Control Module with a soft cloth moistened with a mild detergent solution.

Cleaning the PCE TET and all Cables

Wipe the TET and Cables with a soft cloth slightly moistened with isopropyl (rubbing) alcohol.

Note: ABIOMED recommends that you clean the TET every day.

4 Transferring Support Between the Console and the PCE

WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

CAUTION: Always have 2 power sources connected to the PCE to ensure that you will be able to see and hear alarms if they occur. These power sources can be:

- 2 pairs of Batteries
- 1 pair of Batteries and an AC Power Adapter

CAUTION: Never cover the PCE with clothing.

Covering the PCE may cause it to overheat and operate incorrectly.

CAUTION: Never block the PCE's cooling vents.

Blocking the cooling vents may cause the PCE to overheat and operate incorrectly.

CAUTION: Keep a TET that is connected to the Console or PCE at least 1 foot away from any other TET.

This precaution prevents potential damage to the TET's electronics.

CAUTION: Never place a TET that is connected to the Console on a metal surface.

The metal surface may become overheated, causing a fire hazard.

Transferring Support from the Console to the PCE

When you want to use the PCE instead of the Console, follow the step-by-step procedure listed below. These procedures will ensure that the PCE works correctly to provide energy to your implanted AbioCor Replacement Heart.

There are two different procedures:

- one procedure for using the same TET with the PCE as you use with the Console
- another procedure for changing TETs when you transfer support to the Console

Transferring to the PCE if You Use the Same TET

If you want to use the same TET with the PCE as with the Console, follow this procedure.

1 Insert 2 pairs of fully-charged Batteries into slots in the Battery Bag as shown in Figure 4.1.

- Be sure that the Battery pair indicator lights between the Battery slots in the PCE Battery Bag (Figure 4.1) turn on when the Batteries are in place.
- If the indicator lights do not turn on, be sure the Batteries are plugged securely into place.

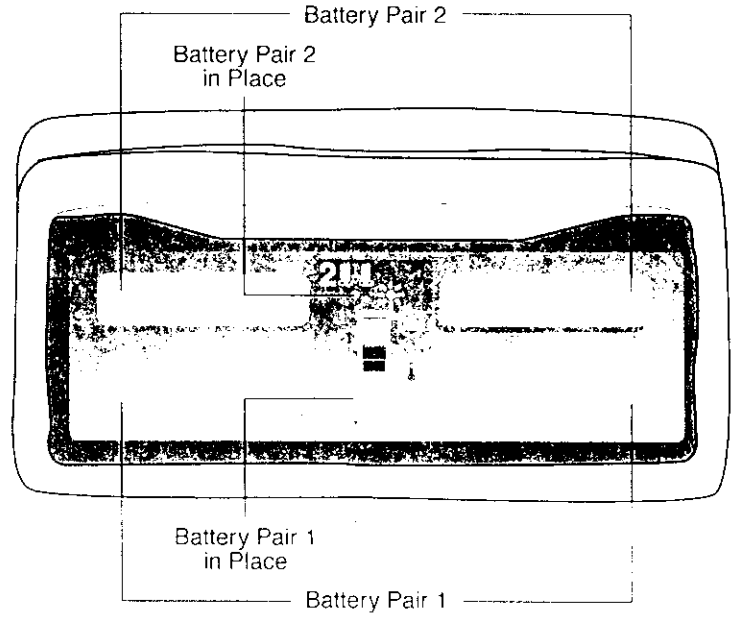

Figure 4.1 Installing Batteries in the Battery Bag

2 Plug the Battery Cable on the Battery Bag into the PCE Control Module as shown in Figure 4.2.

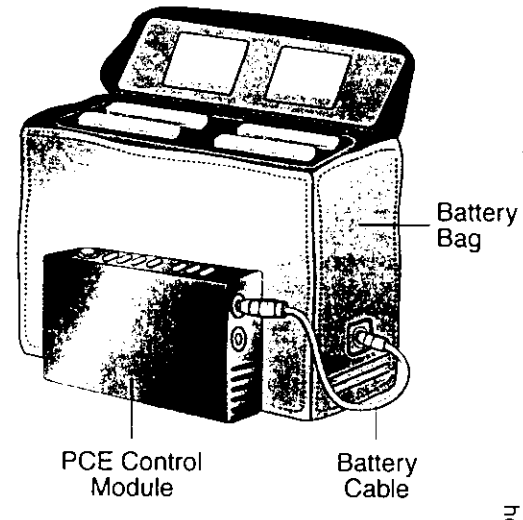

Figure 4.2 Plugging the Battery Cable into the Control Module

3 When the PCE TET alarm sounds, press the Silence Alarm button on the PCE Control Module (Figure 4.3)

The TET alarm light will turn on; this is normal.

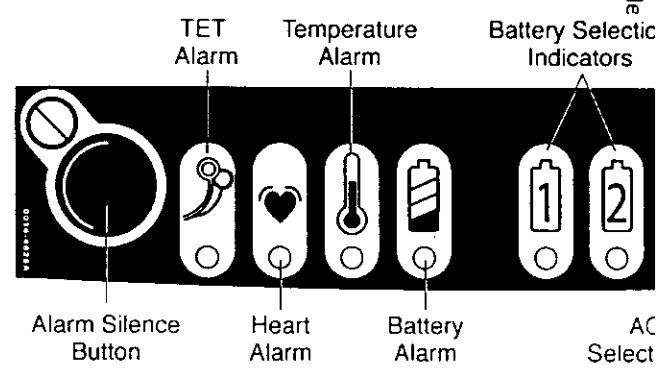

Figure 4.3 Silencing the TET Alarm

4

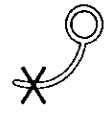

Figure 4.4 Console TET Unplugged

Figure 4.5 Silencing Console Alarms

Unplug the TET from the Console.

- Do not remove the TET or the DuoDerm patch f your chest.
- The "TET Unplugged" symbol appears on the C screen (Figure 4.4) and the TET alarm sounds. T normal.

Press the Console alarm silence button (Figure 4.5

5 Plug the TET connector into the PCE Control Module as shown in Figure 4.6.

The TET alarm light on the PCE Control Module will turn green.

WARNING: The TET is now powered; keep it away from metal surfaces.

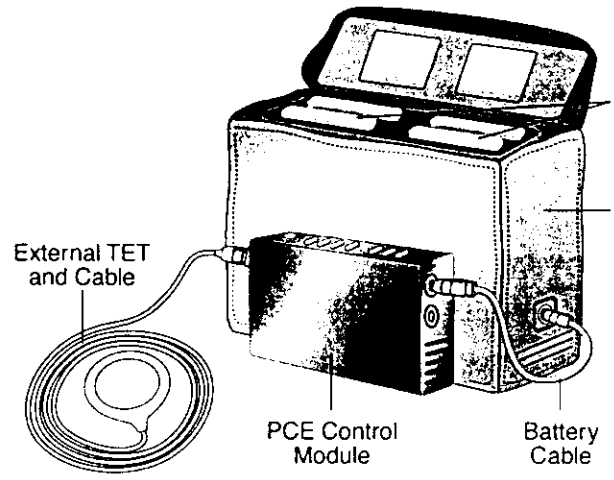

Figure 4.6 Connecting the TET to the PCE C Module

6

Figure 4.7 Console Power Panel After Transfer to PCE

Look at the Implanted Battery section of the Cor Power Panel.

The Implanted Battery icon should be fully fillec gray without a halo around it (Figure 4.7).

This tells you that the Implanted Battery is not tl primary source of power for the Replacement He because the PCE is providing power.

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Figure 4.8 Testing PCE Alarms

Figure 4.9 Checking the Heart Alarm Light

On the Console keypad, press the Test PCE aları (Figure 4.8). The alarm panel displays the follow message:

Testing PCE alarm. You should now hear your F alarm buzzer. If you do not, call your Health Car Provider.

Be sure the Heart alarm light on the PCE Contro turns on (Figure 4.9) and the buzzer sounds.

If you do not hear the PCE alarm, move the RF Communications Module so it is near your abdo the Implanted Controller.

If the alarm does not sound, use a new PCE Con Module.

If the alarm still does not sound, call your health provider.

8

Figure 4.10 Putting the Console on Standby

Press the Console standby mode button (Figure 4.1
the Console into standby mode. This will quiet the
alarms. The Console display shows the following n

**Enter standby mode? Only place the Console into
mode if no one is supported by it! Press the Conso
standby button again to enter standby mode.**

Press the standby mode button a second time to co
that you want to put the Console on standby.

The Console display screen becomes black, with th
standby icon showing in the corner, to tell you th
is in standby mode.

Transferring to the PCE if You Use a Different TET

If you want to change TETs when you transfer support to the PCE, follow this procedure.

1 Insert 2 pairs of fully-charged Batteries into slots in the Battery Bag as shown in Figure 4.11.

- Be sure that the Battery Pair in Place indicator lights between the Battery slots in the PCE Battery Bag (Figure 4.2) turn on when the Batteries are in place.
- If the indicator lights do not come on, be sure the Batteries are plugged securely into place.

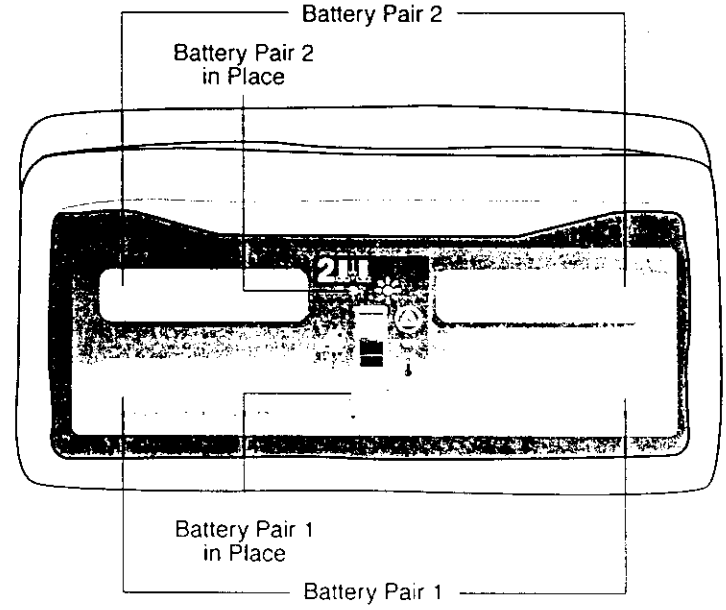

Figure 4.11 Installing Batteries in the Battery Bag

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2 Plug the Battery Cable on the Battery Bag into the PCE Control Module as shown in Figure 4.12.

The PCE TET alarm will sound; this is normal. Press the PCE alarm silence button (Figure 4.17, below) to quiet the alarm.

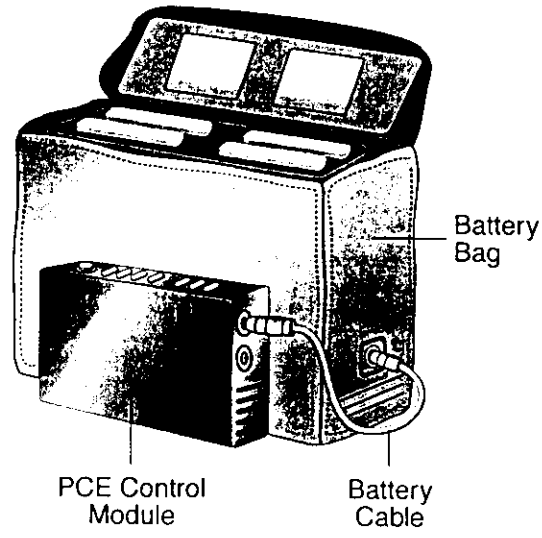


Figure 4.12 Plugging the Battery Cable into the PCE Control Module

3

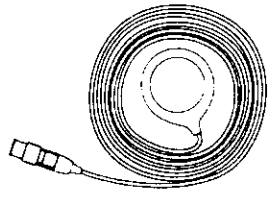


Figure 4.13 Removing the Console TET

Unplug the TET from the Console (Figure 4.13). Be sure to keep the Console TET at least 1 foot away from the PCE TET.

Remove the TET from the DuoDerm Patch on your chest.

4

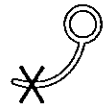


Figure 4.14 Console TET Unplugged

Figure 4.15 Silencing Console Alarms

The "TET Unplugged" symbol appears on tl Console screen (Figure 4.14) and the Conso alarm sounds. This is normal.

Press the Console alarm silence button (Figı

Do the next steps within 2 minutes to minim amount of time that the Implanted Battery is discharging.

5 Plug the PCE TET connector into the PCE Control Module as shown in Figure 4.16.

WARNING: The TET is now powered; be careful to keep it away from metal surfaces.

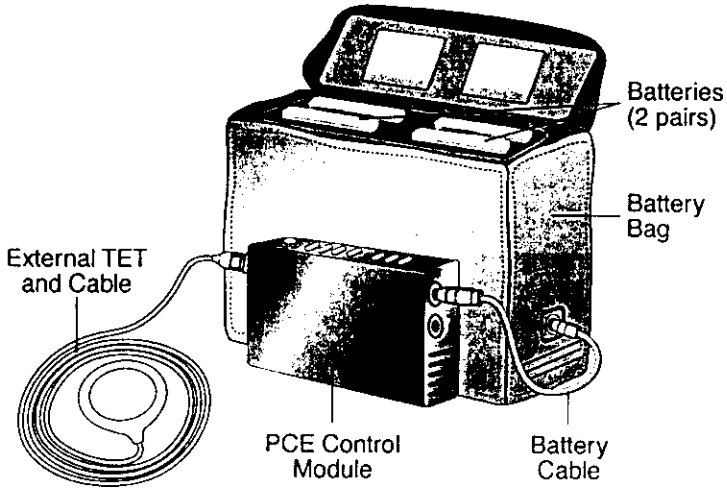


Figure 4.16 Connecting the TET to the PCE Control Module

6 Place the PCE TET on your chest.

Look at the TET alarm light on the PCE Control Module (Figure 4.17); when the light goes off, the TET is correctly aligned.

Secure the TET with the Velcro strips on the DuoDerm patch.

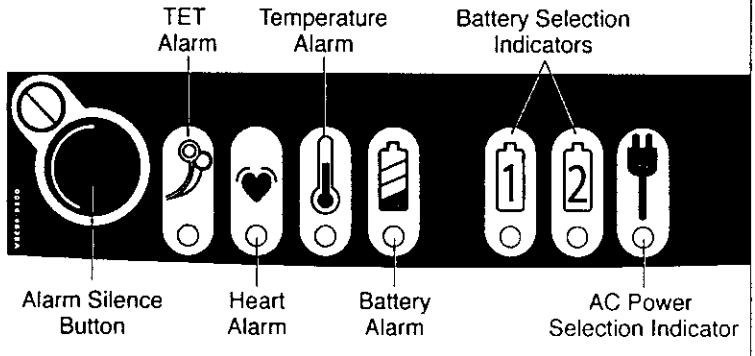


Figure 4.17 Silencing the PCE TET Alarm

7

Figure 4.18 Checking the Console Power Panel

Look at the Implanted Battery section of the Console Power Panel.

The Implanted Battery icon should be fully filled in with gray without a halo around it (Figure 4.18).

This tells you that the Implanted Battery is not the primary source of power for the Replacement Heart because the PCE is providing power.

8

Figure 4.19 Testing PCE Alarms

Figure 4.20 Checking the Heart Alarm Light

On the Console keypad, press the Test PCE alarm button (Figure 4.19). The alarm panel displays the following message:

Testing PCE alarm. You should now hear your PCE alarm buzzer. If you do not, call your Health Care Provider.

Be sure the Heart alarm light on the PCE Control Module turns on (Figure 4.20) and the buzzer sounds.

If you do not hear the PCE alarm, move the RF Communications Module so it is near your abdomen over the Implanted Controller.

If the alarm still does not sound, use a new PCE Control Module.

If the alarm still does not sound, call your health care provider.

9

Figure 4.21 Putting the Console on Standby

Press the Console standby mode button (Figure 4.21) to put the Console into standby mode. This will quiet the Console alarms. The Console display shows the following message:

Enter standby mode? Only place the Console into standby mode if no one is supported by it! Press the Console standby button again to enter standby mode.

Press the standby mode button a second time to confirm that you want to put the Console on standby.

The Console display screen becomes black, with the standby icon showing in the corner, to tell you the Console is in standby mode.

Transferring Support from the PCE to the Console

When you want to use the Console instead of the PCE, follow the step-by-step procedures listed below.

There are two different procedures:

- one procedure for using the same TET on the Console as you used on the PCE
- another procedure for changing TETs when you transfer support to the Console.

Transferring to the Console if You Use the Same TET

If you want to use the same TET with the Console as with the PCE, follow this procedure.

1

Figure 4.22 Bringing the Console out of Standby

Press the standby button on the Console (Figure 4.22) to bring the Console out of standby mode.

If Console alarms sound, use the Alarm Silence button (Figure 4.23) to quiet them.

Figure 4.23 Silencing Console Alarms

2

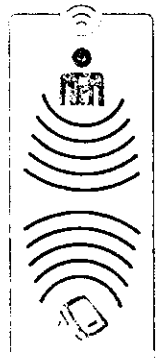


Figure 4.24 Checking the RF Communications Signal

Plug the RF Communications Module into the Console, if it is not already connected.

Position the RF Communications Module to get a good RF communications signal.

Open the RF panel on the Console. Look for green arcs to show that the RF signal is strong in both directions (Figure 4.24). If the signal is not strong, move the RF Communications Module to improve the signal.

Do the next step within 2 minutes to minimize the amount of time that the Implanted Battery is discharging.

3

Unplug the TET from the PCE Control Module.

The PCE TET alarm will turn red and the buzzer will sound. Press the alarm silence button to quiet the alarm (Figure 4.25).

Do not remove the TET from your chest yet.

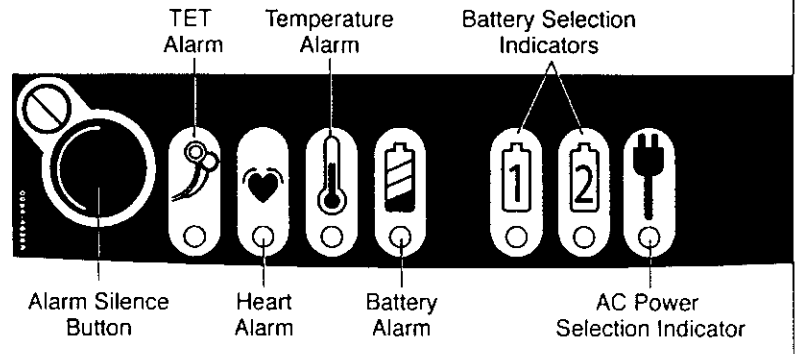


Figure 4.25 Silencing the PCE TET Alarm

4 Plug the TET into the Console TET connector (Figure 4.26)

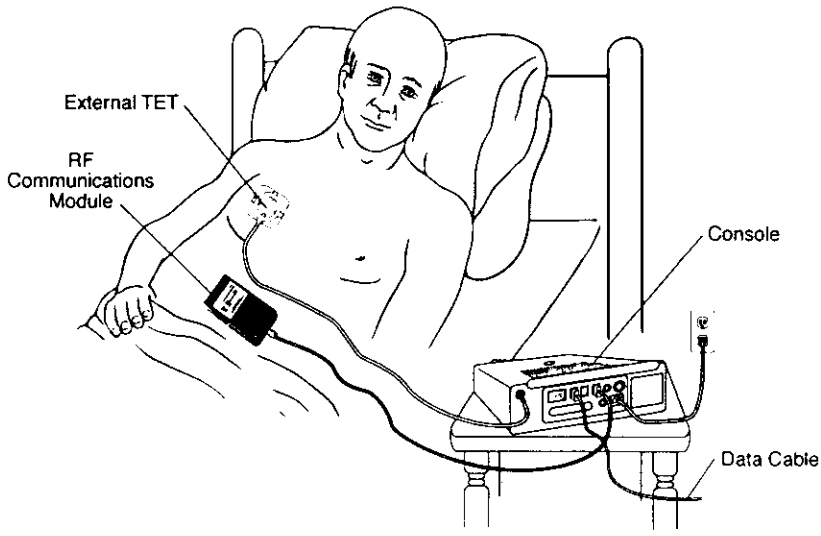


Figure 4.26 Connecting the TET to the Console

5

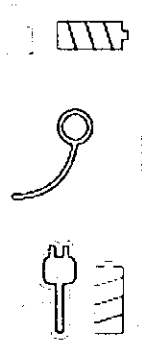


Figure 4.27 Checking TET Alignment and Power on Console Power Panel

Open the Power panel. Using Figure 4.27 as a reference,

- Be sure the TET is aligned correctly (a green TET in the center section of the panel)
- Be sure the system is receiving power from the Console (there is no halo around the Implanted Battery icon).

6 Open the top cover of the PCE Battery Bag (Figure 4.28).

Remove the PCE Batteries.

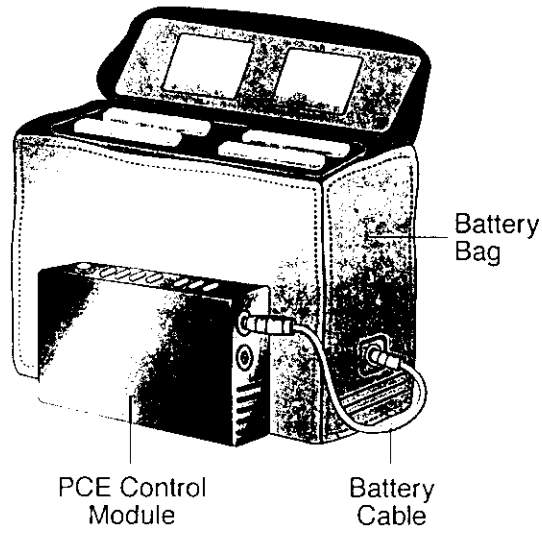


Figure 4.28 Removing the PCE Batteries from the Battery Bag

7 Be sure the Battery Charger is plugged in.

Place the PCE Batteries in the Battery Charger (Figure 4.29).

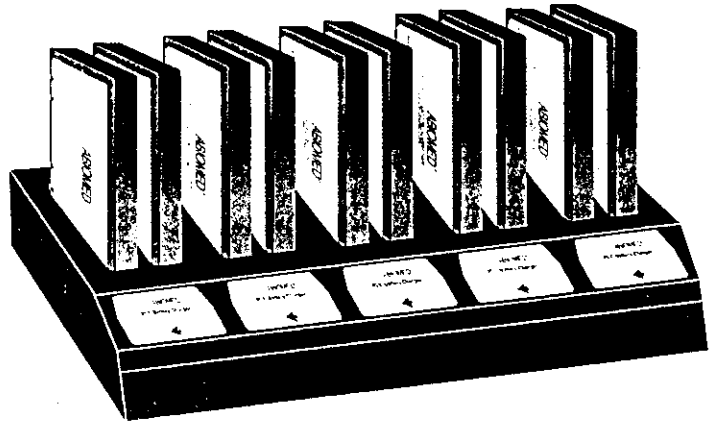


Figure 4.29 Charging the Used Batteries

Transferring to the Console if You Use a Different TET

To transfer support from the PCE to the Console, if you want to use a different TET with the Console, follow this procedure.

CAUTION: Keep a TET that is connected to the Console or PCE at least 1 foot away from any other TET.

This precaution prevents potential damage to the TET's electronics.

CAUTION: Never place a TET that is connected to the Console or PCE on a metal surface.

The metal surface may become overheated, resulting in a fire hazard.

1

Figure 4.30
Bringing the Console out of Standby

Press the standby button on the Console (Figure 4.30) to bring the Console out of standby mode.

2

Figure 4.31
Checking the RF Communications Signal

Plug the RF Communications Module into the Console, if it is not already connected.

Position the RF Communications Module to get a good RF communications signal.

Open the RF panel on the Console. Look for green arcs to show that the RF signal is strong in both directions (Figure 4.31). If the signal is not strong, move the RF Communications Module to improve the signal.

Do the next step within 2 minutes to minimize the amount of time that the Implanted Battery is discharging.

3 Unplug the TET from the PCE Control Module. Remove the PCE TET from your chest. Do not remove the DuoDerm patch.

4 Place the Console TET on your chest.

Secure it with the Velcro strips on the DuoDerm patch.

5 The PCE TET alarm will light and the buzzer will sound. Press the alarm silence button to quiet the alarm (Figure 4.32).

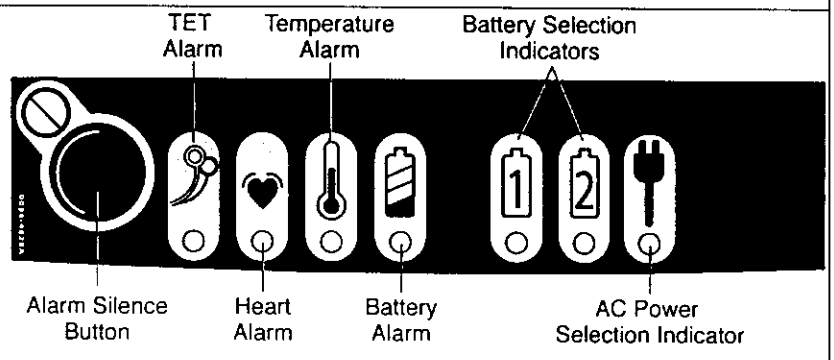


Figure 4.32 Silencing the PCE TET Alarm

6 Plug the Console TET into the Console TET connector (Figure 4.33)

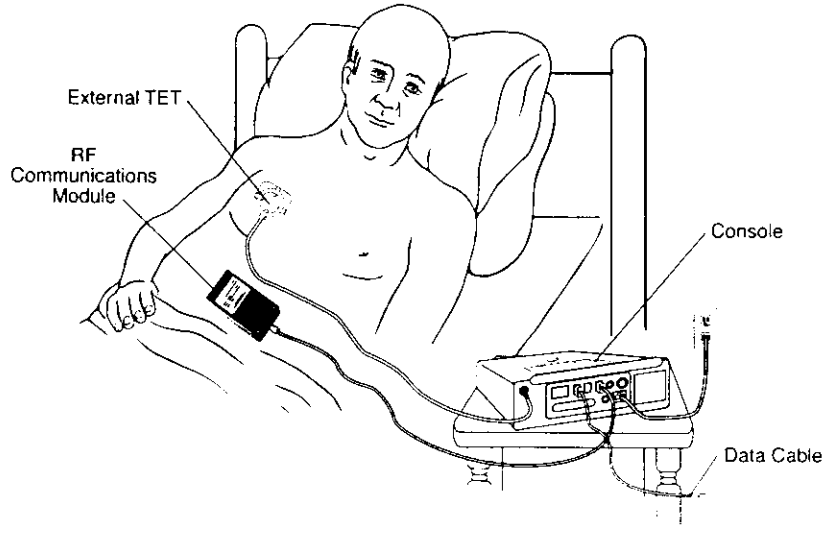


Figure 4.33 Connecting the TET to the Console

7 Open the Power panel. Using Figure 4.34 as a reference:

- Be sure the TET is aligned correctly (a green TET in the center section of the panel) Reposition the TET on your chest if the TET is not correctly aligned.
- Be sure the system is receiving power from the Console (there is no halo around the Implanted Battery icon).

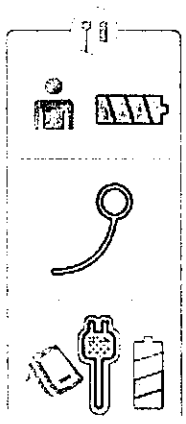


Figure 4.34 Checking TET Alignment and Power on Console Power Panel

8 Open the top cover of the PCE Battery Bag (Figure 4.35).

Remove the PCE Batteries.

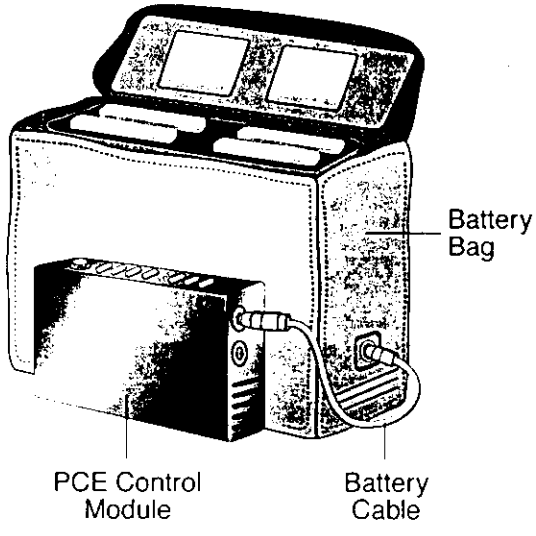


Figure 4.35 Removing the PCE Batteries from the Battery Bag

9 Be sure the Battery Charger is plugged in.

Place the PCE Batteries in the Battery Charger (Figure 4.36).

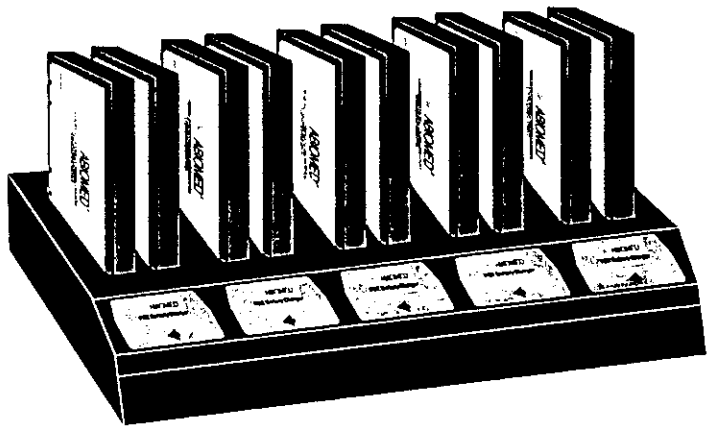


Figure 4.36 Charging the Used Batteries

5 PCE Alarms

What are the PCE Alarms?

The PCE Control Module monitors the AbioCor System's implanted components and the PCE Batteries to ensure that all the parts of the system are working correctly.

If a problem is detected, the PCE Control Module turns on an alarm indicator light and sounds an alarm.

To quiet the alarm temporarily, press the Alarm silence button on the PCE Control Module. (See Figure 5.1.) If you are unable to resolve the alarm within 2 minutes, it will sound again.

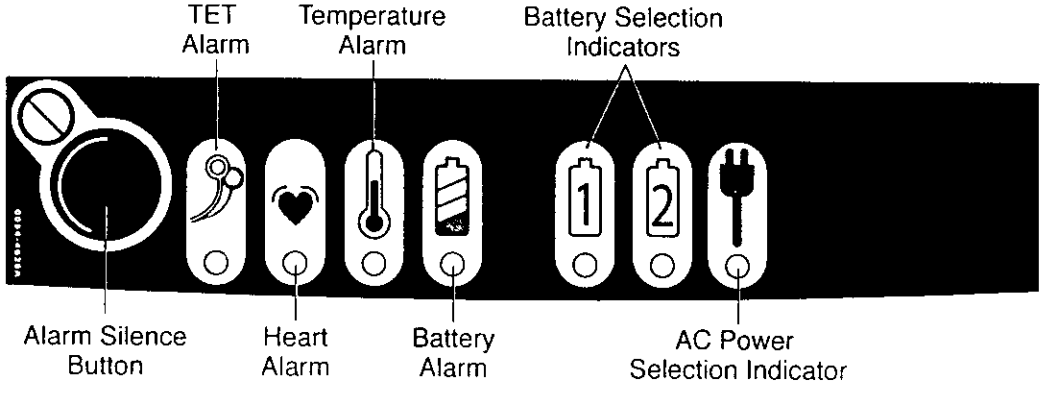


Figure 5.1 PCE Control Module Panel

PCE Battery Bag Alarms

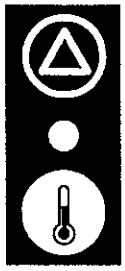
Table 5.1 lists the PCE Battery Bag alarms that you can see on the panel inside the PCE Battery Bag and the actions you should take if they occur.

WARNING: When using the PCE, you must always have at least one of the following backup units available within 10 minutes:

- a PCE Battery Bag and 2 pairs of fully-charged Batteries
- a fully-charged AbioCor Console

If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.

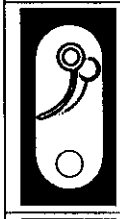
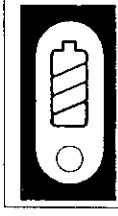
Table 5.1 PCE Battery Bag Alarms

Icon	Name	Description	What to Do
	PCE Battery Bag Power and Temperature Alarms	The light between the triangle icon and thermometer indicates a problem in the PCE Battery Bag. The light may be red or yellow.	
		A RED light indicates a serious Battery Bag power problem.	Connect the AC Power Adapter right away. If the light stays RED for more than 1 minute, exchange the PCE system for a new unit.
		A YELLOW light indicates that the PCE has overheated.	Be sure that the PCE is in an open area, out of the sun, and that the cooling vents on the side of the Battery Bag are not covered by a coat or blocked by anything around them. If the light stays YELLOW for more than 1 minute, exchange the PCE for a backup unit.

PCE Control Module Alarms

The alarms displayed by the PCE Control Module are explained in Table 5.2.

Table 5.2 PCE Control Module Alarms

Icon	Name	Description	What to Do
	TET alarm	The red light indicates that the PCE TET is out of alignment with the Implanted TET or unplugged. An alarm sound is also heard.	Reposition the PCE TET. If the light turns green, alignment is OK.
	Heart alarm	The light indicates that there is an alarm condition on the Implanted Replacement Heart, Implanted Controller, or Implanted Battery. An alarm sound is also heard.	Use the Handheld Monitor or position the RF Communications Module over the Implanted Controller and look at the Console display to see what is wrong If a setting needs to be changed, use the Console.
	Temperature alarm 	The light indicates that the temperature inside the PCE Control Module is too high. An alarm sound is also heard. **WARNING:** If a PCE temperature alarm condition persists for more than 1 minute, transfer control from the overheated PCE to a backup PCE or the Console. If the PCE fails and no backup unit is available, the AbioCor System may stop working, resulting in death.	Be sure that the PCE is in an open area, out of the sun. Be sure that the cooling vents on the side of the PCE Control Module are not covered by a coat or blocked by anything around them. If the PCE remains overheated for more than 1 minute (indicated by the temperature alarm lights and sound), transfer control from the overheated PCE to a backup PCE or the Console.
	Battery alarm	The light indicates that the charge on the selected pair of Batteries is low. An alarm sound is also heard.	Switch to the other pair of Batteries or connect the AC Power Adapter. Replace the low Batteries with freshly charged ones as soon as possible.

Appendix: Federal Communications Commission (FCC) Notice

AbioCor Components	Notice
AbioCor Console	This device complies with Part 18 of the FCC Rules.
PCE Control Module	This device complies with Part 18 of the FCC Rules.
RF Communication Module	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Handheld Monitor	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Implantable Controller	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.

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Professional Labeling

ABIOMED

AbioCor® Implantable Replacement Heart

Instructions for Use

For Humanitarian Use:
Authorized by Federal law for use in treatment of patients with irreparably damaged hearts, at imminent risk of death with no other treatment options. The effectiveness of this device for this use has not been demonstrated.

IMPORTANT NOTICE: Read this ***entire*** manual before using the AbioCor Implantable Replacement Heart (AbioCor). The AbioCor is to be used only in accordance with this manual.

Information contained in this document is subject to change without notice.

Manufactured by **ABIOMED, Inc.**
22 Cherry Hill Drive
Danvers, MA 01923
USA
978-777-5410

24-Hour Emergency Technical and Clinical Support: 1-800-422-8666

1 System Description

The AbioCor® Implantable Replacement Heart System is intended to replace the patient's diseased native heart. It is designed for patients whose hearts are irreparably damaged or who are at imminent risk of death by heart failure of both the left and the right side of the heart.

The System can be divided into the Implanted system (Figure 1-1) and the External system. The Implanted system consists of the Thoracic Unit, the Implanted Controller, the Implanted TET, and the Implanted Battery. The External system consists of the AbioCor Console and the Patient Carried Electronics (PCE).

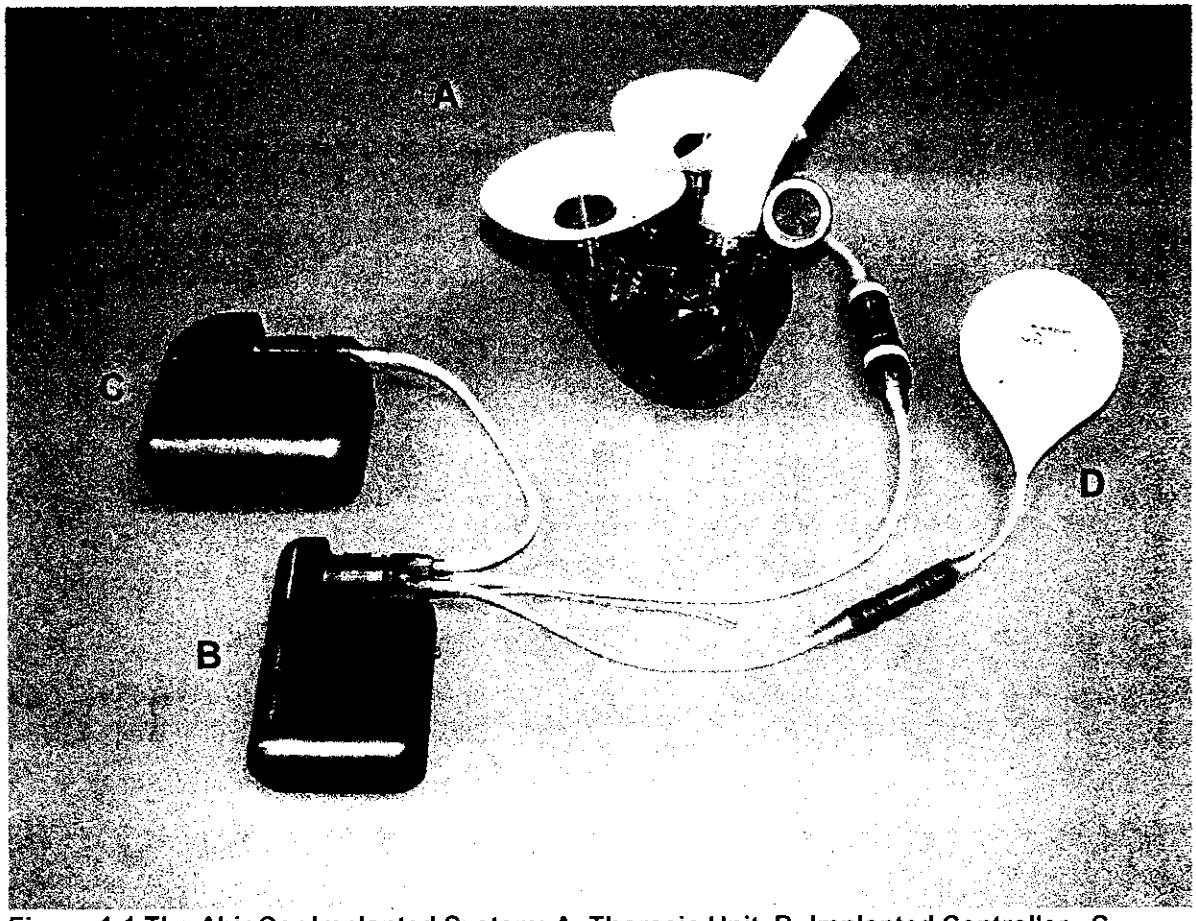


Figure 1-1 The AbioCor Implanted System; A- Thoracic Unit, B- Implanted Controller , C- Implanted Battery, C- Implanted TET.

1.1 Thoracic Unit

The Thoracic Unit (Figure 1-2) consists of two blood pumps sealed to and separated by the Energy Converter. Each blood pump can be seen as a hard-shelled chamber containing a sac filled with blood. The space between the sac and the Energy Converter is filled with hydraulic fluid.

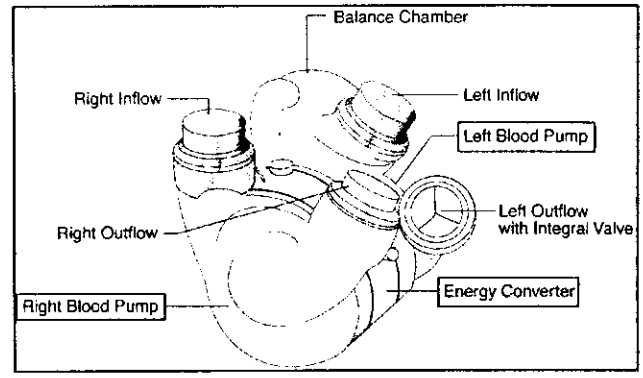


Figure 1-2 AbioCor Thoracic Unit

The Energy Converter moves hydraulic fluid from one side to the other, squeezing the sac in one pump and forcing blood out of it. Simultaneously, blood is actively drawn into the other pump, filling it for the next cycle. The Energy Converter pumps hydraulic fluid in each direction alternately so that the left and the right blood pump alternately fills and ejects blood.

1.2 Implanted Controller

The Implanted Controller is the brain of the Implanted system. It performs several functions:

- monitoring of the Thoracic Unit and the other implanted components
- control of the Thoracic Unit
- communication with the external components (the AbioCor Console or Patient-Carried Electronics) and transmission of alarms

The Implanted Controller contains the control electronics in a hermetically sealed titanium case. It is implanted abdominally, outside the peritoneum, on the patient's left side between the sub-costal and iliac regions.

1.3 Implanted Battery

The Implanted Battery, when new and fully charged, contains enough electrical energy to drive the AbioCor System for approximately 60 minutes with no external power supply. This allows the patient to function without a Console or PCE for short periods. The actual time of operation on the Implanted Battery depends on the age

and charge of the battery and on the blood flow rate provided by the AbioCor System.

The Implanted Battery is implanted abdominally, outside the peritoneum, on the patient's right side between the subcostal and iliac region. In this location, the battery can be replaced by a minor surgical procedure. Because the AbioCor System can get power externally, through the TET, the battery can be replaced without interrupting the operation of the AbioCor System.

The Implanted Battery recharges automatically whenever the implantable components are drawing power from the TET.

1.4 Implanted TET

The Implanted TET receives electrical energy in the form of radio waves from the External TET and converts it to the DC power used by the rest of the AbioCor System.

The Implanted TET is positioned in a subcutaneous pocket, usually in a sub-clavicular location. The exact location depends on the patient's size and other anatomical considerations.

The Implanted TET is the primary power source for the AbioCor System's implanted components. Because the radio waves used can pass through a small thickness of human tissue, no percutaneous connections are needed. In addition, the Implanted TET can transmit alarm signals when the TET Alarm Channel is in use.

1.5 AbioCor Console

The AbioCor Console (Figure 1-3) is the primary external component of the AbioCor System. It serves as the primary user interface in the clinical setting and provides power and data communications to the internal components, and is the interface for other patient monitoring equipment, data logging, networking, remote monitoring, and other external functions. The Console transmits power via the TET, and communicates via the RF Communications Module.

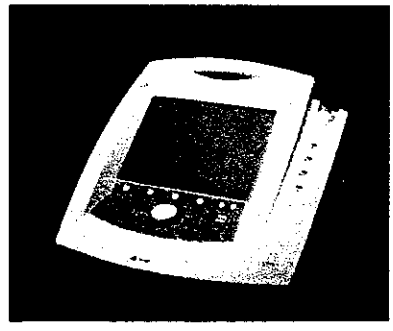


Figure 1-3 The AbioCor Console

1.6 Patient-Carried Electronics (PCE)

The Patient-Carried Electronics (Figure 1-4) is a portable system that provides battery power to the implanted AbioCor System through an External TET. The External TETs used with the PCE are same as the ones used with the Console. The Hand Held Alarm Monitor (Figure 1-5) is a PDA device that can receive information from the Implanted system (e.g. alarms, implanted battery status, flow, beat rate, etc) over the RF link. The PCE is carried in a Nylon Battery Bag that can be worn over the shoulder. The PCE, together with a Hand Held Alarm Monitor, affords freedom away from the Console for extended periods of time.

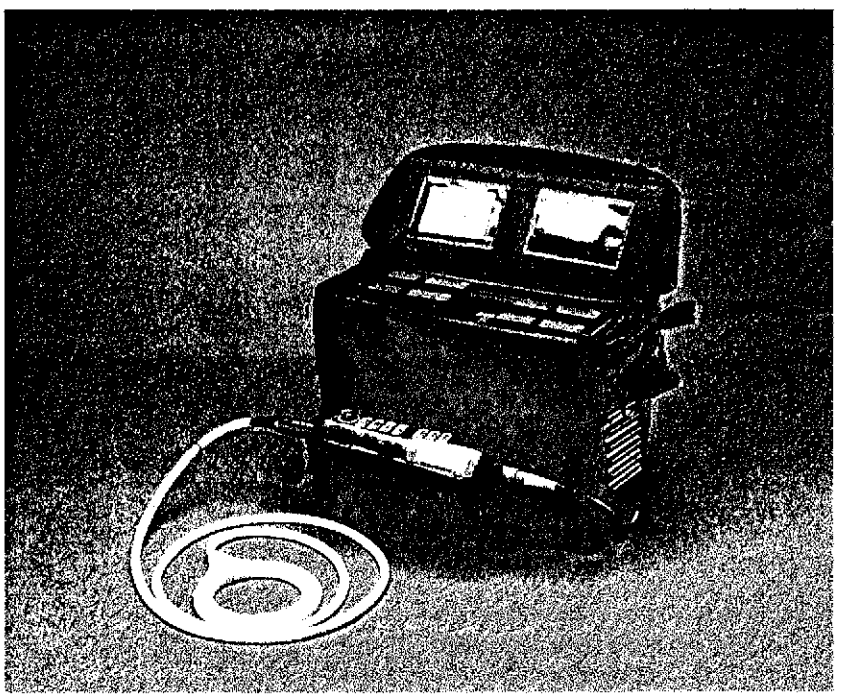


Figure 1-4 Patient Carried Electronics (PCE)

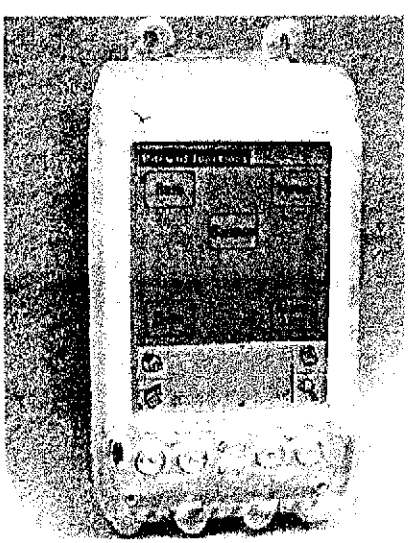


Figure 1-5 Hand Held Alarm Monitor

The relationship of the Implanted components and the External components are illustrated in Figure 1-6. The Implanted components receive power and user command signals from either the AbioCor Console or the Patient-Carried Electronics (PCE).

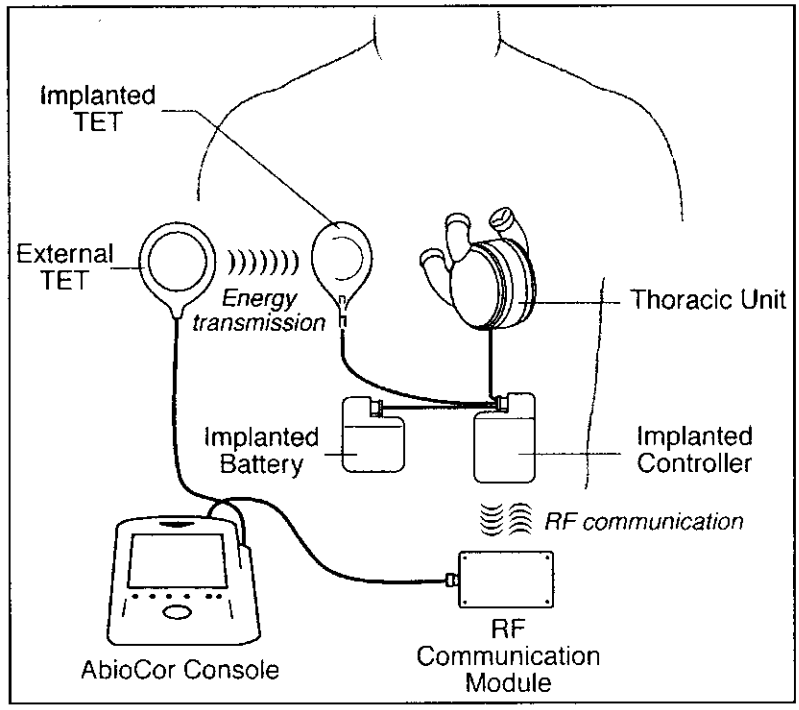


Figure 1-6 Relationship of Internal components to External components of the AbioCor system.

2 Indications and Contraindications for Use

2.1 Who is the AbioCor for?

The AbioCor® is indicated for use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who

- are less than 75 years old,
- require multiple inotropic support,
- are not treatable by LVAD destination therapy, and
- are not weanable from biventricular support if on such support.

The AbioCor is intended for use in patients with irreversibly failing hearts who cannot benefit from existing treatment methods, such as surgical intervention, drug therapy, or approved devices and with heart failure of both the left and right sides of the heart. Heart failure is a condition in which the heart muscle has weakened to the point that it has difficulty pumping the required minimum amount of blood to the

rest of the body. Heart failure generally develops over time from many causes such as injury to the heart muscle resulting from heart attacks, untreated high blood pressure putting excess load on the heart, and/or leaky heart valves making the heart work harder but not efficiently. These conditions alone or together weaken the heart muscle over time so it is not able to deliver the required amount of blood.

Because it is a device approved by Federal (USA) law for use on a humanitarian basis, the AbioCor, at this time, can only be offered to patients who are extremely ill with no other treatment options that have both left and right side heart failure (See Appendix A).

2.2 Screening Evaluations

Consent will be requested to collect some medical information.

The first type of information includes test results from recently conducted medical procedures. This information will be used to see if you meet the selection criteria.

The second type of information will be obtained from Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scans. The imaging data from the scan will be used to see if the AbioCor can possibly fit in your chest.

2.3 Contraindications for the AbioCor

The AbioCor should not be used in patients with:

- Presence of other irreversible end organ dysfunction that would compromise survival
- Inadequate psychosocial support
- Preoperative noninvasive anatomical assessment indicating inadequate fit (i.e. thoracic volume is unable to accommodate the device)
- Presence of coagulation disorders

3 Candidate Awareness of Life on the AbioCor

3.1 What are the Potential Complications?

Surgery to implant an AbioCor Implantable Replacement Heart, and use of the AbioCor System, are associated with a variety of potential complications. Most of the complications that may occur with the AbioCor System are similar to those associated with other major cardiac surgery such as a heart transplant or ventricular assist device (VAD) implantation.

Based on the experience of the AbioCor initial clinical trial, the following complications and adverse events can potentially occur in patients implanted with the AbioCor:

- Bleeding events may occur that require additional surgery, procedures or blood transfusions
- Surgery is required if your internal battery or TET needs replacement
- Infection may be a complication during your recovery period in the hospital
- Kidney, liver, and lung complications may occur and thus may necessitate treatments to reverse
- Recovery can be extended in duration and may lead to depression and other psychiatric episodes
- An extended recovery period may necessitate the use of feeding tubes or other means of ensuring adequate nutrition
- Strokes may occur that could result in incapacitation and death
- Device may stop suddenly leading to death

3.2 How will the AbioCor Affect Daily Living Activities

This section presents what patients might expect in their daily lives having recovered from their implant surgeries. Living with the AbioCor supporting their lives, patients will encounter certain situations, some unique to this device and others common to other medical conditions. Based on the experience of the AbioCor initial clinical trial, the following situations/considerations were faced by implanted patients:

- It is desirable that each patient has a constant companion to provide various types of support
- Patients and their support companion will learn to recognize and manage situations that cause the AbioCor system to alarm.
- Patients and their support companion will be required to manage their batteries including charging them, exchanging them, being aware of how long they have been running and heeding their warnings.
- Patients and their support companion will always have to make sure they have backup equipment nearby.
- Patients will have to take their blood thinning medications diligently as instructed by their healthcare providers.
- Patients will have to pay attention to the maintainence of proper external TET positioning so that power supply to the internal AbioCor components is not compromised.
- Patient may experience sleep disruptions due to alarms, such as a TET dislodgements, etc.
- Physical activity may be limited in certain patients.

- Some patients may experience chronic pain from various causes, such as slow healing wounds, etc.
- Patients are allowed to take baths, showers (instructions will be given), but not to do deep water swimming.
- Patients will have to avoid travel that exposes them to changes in altitudes of greater than 2 500 feet (eg. commercial air travel is restricted)

These restrictions may be alleviated with additional clinical experience.

3.3 What were the Initial Clinical Study Results?

3.3.1 Objectives

For those subjects implanted with the AbioCor®, the initial evaluation of safety and potential effectiveness was to be assessed at 60 days post-implantation. The study would be considered successful if AbioCor® support extended life to 60 days without unacceptable complications, adverse event rates, or quality of life (QOL) deficits in five implanted patients.

3.3.2 Methods

Candidate selection proceeded in two stages, a screening stage and an implant consent stage. During the screening stage, a comprehensive medical assessment was performed. This assessment included determining the severity of a candidate's heart failure and the potential fit of the device in the patient's thoracic cavity.

Candidates eligible for the trial were those who were not eligible for heart transplantation based on the center's criteria at the time of screening, were in biventricular failure not treatable with implantable LVAD, and were under optimal medical management yet; the clinical judgment of the treating physicians was that patients were unlikely to survive for a month. Patients with irreversible end-organ failure or inadequate psychosocial support were excluded from the trial.

Candidates were excluded if the prognosis for survival was greater than 30% within the next 30 days. The prognosis of survival was based on a clinical judgment of a combination of factors including hemodynamic status, cardiac conditions and end organ status.

To assess the potential for anatomic fit, MRI or CT scans from candidates were used to reconstruct the internal chest dimensions and the anatomy of the patient. A virtual surgery was performed to remove the ventricles and place the AbioCor® in the vacated space. Three critical observations were made to insure fit. The AbioCor® device had to remain within the rib cage, while not interfering with the left bronchus and the left pulmonary veins.

If a candidate passed all the established criteria, a patient advocate would be available to participate in the informed consent process if desired. Although direct patient consent was preferred, in cases where this was not practical, a legally authorized representative consented on the subject's behalf.

3.3.3 Description of Enrolled Subjects

Fourteen subjects were enrolled in the trial at 4 centers. Twelve of the 14 subjects were enrolled at 2 centers. All candidates were males due primarily to fit constraints. Table 3.1 provides a summary of subject demographics. The mean age of this initial cohort was 67 ± 7.9 years, ranging between 51 and 79 years old. The percentage of subjects excluded from transplant due to age was 43% (6/14), to irreversible pulmonary hypertension was 29% (4/14), to malignancy was 14% (2/14), and to multiple comorbidities including diabetes, neuropathy, renal dysfunction, and hepatic dysfunction, was 14% (2/14). The Body Surface Area (BSA), body weights, and heights are also given in the table.

	Average	Stdev	Min	Max
Age (years)	67	7.9	51	79
BSA (M^2)	1.97	0.15	1.72	2.24
Height (cm)	180.	6.2	170.2	189
Weight (kg)	78.1	10.9	60.8	96.3

Table 3.1. Subject Demographics (n=14)

The preoperative cardiac conditions and comorbidities of subjects are summarized in Table 3.2. All subjects were in New York Heart Association (NYHA) Class IV heart failure primarily of ischemic origin (12/14) with two being idiopathic. All subjects were bed bound. A majority of the subjects had prior cardiac operations, pacer or Automatic Implantable Cardioverter Defibrillator (AICD) implanted, and/or required Intra-Aortic Balloon Pump (IABP) support. Pulmonary hypertension and renal dysfunction were the two primary comorbidities. Ten of the fourteen candidates required IABP support.

Pre-implant Cardiac Condition or Comorbidity	# of Subjects with Condition (n=14)
NYHA Class IV	14
Re-op	10
Pacer/AICD	10
IABP	10

Ventilator Support	4
Pulmonary Hypertension	8
Renal Dysfunction	9
Liver Dysfunction	4
Diabetes	6

Table 3.2. Pre-Operative Conditions

Pre-operative hemodynamics are summarized in Table 3.3. All data were collected within two weeks of implantation. The data in the table represent the average across subjects of a single time point measurement pre-operatively. These averages may not fully reflect subjects' hemodynamics as illustrated by the central venous pressure. The central venous pressure (CVP = average 11 mmHg) spanned a broad range reflecting patients being actively volume managed by infusion, diuresis, and vasoactive drugs. The wedge pressure was elevated (LAP = average 19.9 mmHg).

Mean systemic pressure was 75 ± 9 mmHg. The mean cardiac index was 2.1 ± 0.5 L/min•M^2 under such maximal inotropic support concurrent with counterpulsation support. High levels of inotropic support averaging 2.5 ± 1.0 drug types were needed to maintain marginal cardiac output and systemic pressure.

		Average	Stdev	N
PAP	(mmHg)	34	6.6	14
AoP	(mmHg)	74	6	14
CVP	(mmHg)	11	6.4	14
PCWP	(mmHg)	19.9	5.5	14
Cardiac Index	(L/min-M^2)	2.1	0.5	14
Cardiac Output	(L/min)	4.3	1.2	14
Ejection Fraction	(%)	18.6	3.5	14
PVR	(dynes-sec/cm^5)	305	107	12
SVR	(dynes-sec/cm^5)	1231	349	14

Table 3.3. Pre-operative Hemodynamics

The systemic vascular resistance (SVR) was 1231 dyne•sec/cm^5 spanning a broader range than normal indicative of both hypotensive and hypertensive conditions of multiple etiologies. The pulmonary vascular resistance (PVR) was elevated at 305 dyne•sec/cm^5.

Table 3.4 shows the mean dosages for the inotropes used. The dosages were in the medium to high range.

Inotrope	Mean Dosage	Standard Deviation	Number of Patients
Dobutamine - (µg/kg/min)	7.89	4.08	8
Dopamine - (µg/kg/min)	9.16	10.53	6
Milrinone - (µg/kg/min)	0.43	0.24	12
Epinephrine - (µg/min)	3.3	--	1
Norepinephrine - (µg/min)	9.11	--	1
Digoxin - (mg/day)	0.14	0.05	7

Table 3.4. Pre-operative Inotrope Dosages (n=14)

Pre-operative blood chemistry is summarized in Table 3.5. The albumin and sodium were low but creatinine and total bilirubin were elevated.

		Average	Stdev	Min	Max	N
Na	(mEq/L)	131.7	6.4	120	141	14
Albumin	(g/dl)	2.8	0.7	2	3.9	11
Creat	(mg/dl)	1.7	0.7	1	3	14
BUN	(mg/dl)	45.1	30.2	16	110	14
T bil	(mg/dl)	1.7	1.8	0.5	7.4	14
ALT	(mg/dl)	63.5	100.2	3	333	14
AST	(mg/dl)	73.1	125.8	10	491	14
Glucose	(mg/dl)	116.7	39.5	59	186	14

Table 3.5. Pre-operative Blood Chemistry

All subjects entered into the trial met the inclusion criterion of biventricular failure as the basis for exclusion from potential implantable LVAD support. In addition, candidates were excluded if the prognosis for survival was greater than 30% within the next 30 days. The inotrope requirements of AbioCor® subjects averaged 2.5 inotropes.

3.3.4 Results

Twelve of the fourteen subjects were implanted with the AbioCor® at two centers, with one subject being implanted at each of the other two centers. Twelve subjects survived the implant surgery while two did not. All four centers were successful in their first implant. The twelve subjects were supported by the AbioCor® for a cumulative support duration of 5.2 years. The mean individual survival time for all fourteen subjects was 4.5 months, ranging from 0 to 512 days. The median was 3.6 months. Figure 3.1 shows the support duration for each subject.

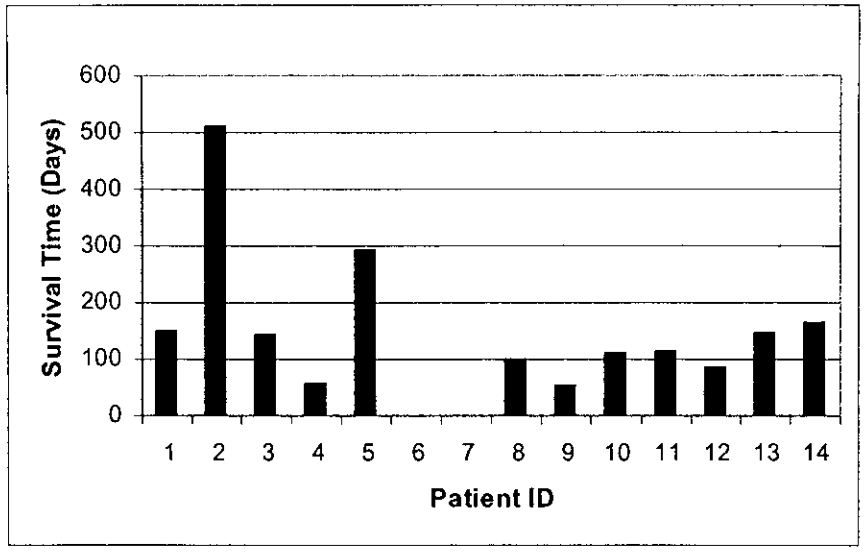


Figure 3.1. Support Duration for each subject

Adverse Events

Recovery was a lengthy process for these subjects. Table 3.6 lists the major adverse event types experienced by the subjects. Event rates are given in reported incidents per subject per month. The Transient Ischemic Attack (TIA) category includes events that resolved within 24 hours. There were many surgical bleeding events, such as tamponade, occurring during the first few weeks post operatively. The most common events were bleeding and infection unrelated to the device, and respiratory complications. These were followed by neurologic, renal, and hepatic complications.

Event Type	# of Subjects Who Suffered Events	Event Rate (per subject•month)	Total # of Events
CVA*	9	0.29	18
TIA*	3	0.05	3
Non-surgical bleeding	9	0.41	26
Surgical bleeding	10	-	42
Sepsis	2	0.03	2
Infection	11	0.52	33
Hepatic	6	0.11	7
Renal	9	0.13	8
Respiratory	11	0.37	24

*Three subjects had both CVA and TIA and are included in both categories.

Table 3.6. Adverse Event Rate (n=12)

The propensity for bleeding was high for AbioCor® subjects. 10 of 12 subjects could not tolerate the recommended level of anticoagulation (INR>2.5 or PTT>50 sec) more than 60% of the time, and of these 10 subjects, seven could not tolerate more than 80% of the time. Although the infection rate was high, none of the incidents were related to device infection.

There were two septic events associated with the AbioCor ® subjects, one as a sequella to a massive abdominal bleeding episode. This episode was caused by a femoral vein puncture during a dialysis catheter exchange. The second event occurred in a subject whose suture line did not heal following surgery.

In six subjects, CVA was the cause that led directly or indirectly to the withdrawal of support. The time from CVA to support withdrawal was typically a small fraction of the total support time. The mean time between the terminal CVA event and the withdrawal of support was 17.3 days. Figure 3.2 shows the total duration of support for these six subjects and the time between the CVA event and the withdrawal of support (shown as solid part of the bar). This latter time span was governed either by signs of recovery based on medical reasons which later reversed course or by family members.

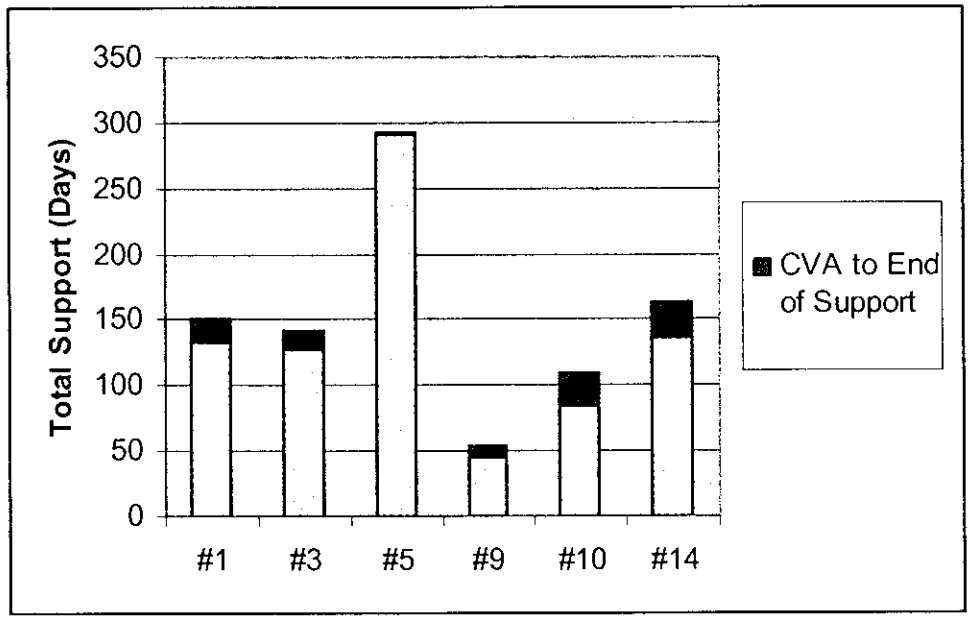


Figure 3.2. Support Time and CVA to End of Support

Two factors contributed to the CVAs. Tissue contact with the inflow structure was the most likely cause of thrombus formation and subsequent embolic complications despite appropriate levels of anticoagulation and antiplatelet therapy as observed in 3 of the first 5 subjects implanted. Following the identification of the tissue contact problem and the elimination of the tissue contact with the inflow structure, two subjects who were adequately managed with anticoagulation and antiplatelet

therapy were free from CVA complications, while all 5 subjects who could not be anticoagulated adequately had CVA events. Adequate therapy was defined as a subject having >20% of the time being on either coumadin or heparin that resulted in INR > 2.5 or PTT > 50 sec, or being dosed with two or more baby aspirin tablets (> 81 mg) or at least one tablet of clopidogrel.

Device Malfunction-Related Adverse Events

There were two device malfunction-related subject deaths. A subject died due to a membrane wearing out at 17 months, an anticipated wear out mode at operating times of around one and one-half years. The subject declined the option for a device replacement. A second subject died due to a motor-bearing stoppage at 4.8 months. The cause was traced to a combination of factors leading to system operation outside of the system design. Corrective actions have been implemented to avoid such future combinations of circumstances.

Outcome

Two patients did not survive the operative procedure. For the remaining twelve AbioCor ® subjects in the trial, all lived out the remaining portions of their lives on the device. Support to six of the twelve subjects was withdrawn secondary to CVAs. There were two device failures. Four subjects died of multi-organ failure or sepsis.

The two operative deaths were due respectively to uncontrollable bleeding and pulmonary embolus caused most likely to the use of factor concentrates following protamine reversal. Three of the six CVA-related deaths were due to inflow structure thrombosis, while the remaining three were due to factors preventing adequate anticoagulation of the subjects. One device failure was due to membrane wear and the other due to motor stoppage. The causes of those subjects who died of multi-organ failure or sepsis were secondary to (1) a vein puncture from a dialysis catheter leading to abdominal bleeding, aspiration, and subsequent sepsis, (2) unhealed suture wound, and (3) two cases of pre-existing hepatic dysfunction that failed to reverse.

Post-operative Clinical Performance

AbioCor® was able to immediately correct cardiac output failure. Figure 3.3 shows the pump output provided by the AbioCor®. The figure contains data for the twelve supported subjects. The figure includes the preoperative average of each parameter (▪) as the first datum plotted. Daily averages are plotted along with the respective standard deviations. The number of contributing subjects decreased as time progressed. Patient cardiac output increased by 50% on the AbioCor®.

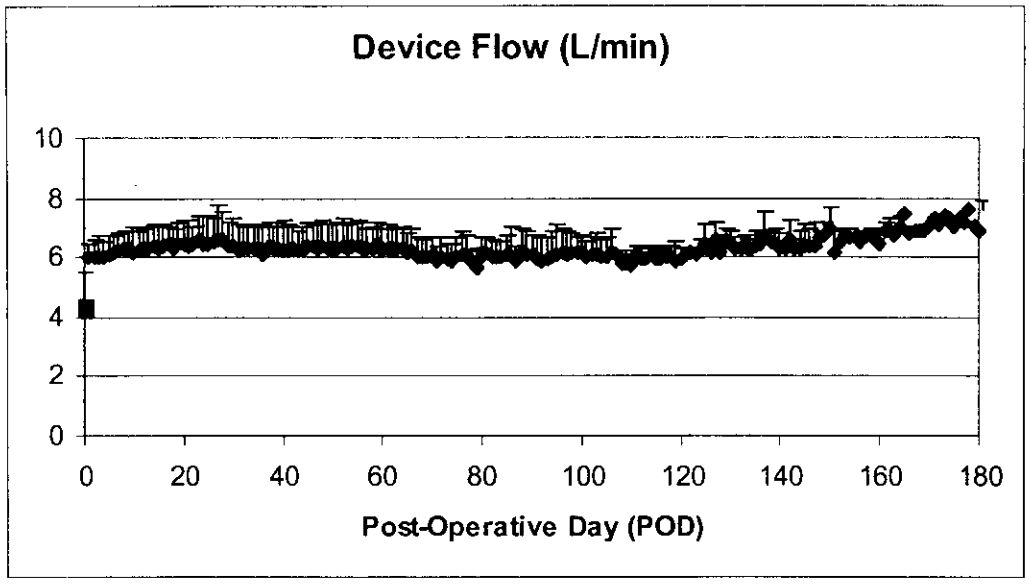


Figure 3.3. Pump Output

Hemodynamic monitoring was maintained only for a short duration post operatively mainly to avoid complications associated with extended use of indwelling lines. Table 3.7 shows the means of the pre vs post AoP, LAP, and CVP for the subjects. The increased AoP and the reduction in the LAP were expected on the AbioCor ®. CVP did not decrease.

	Pre-op Mean and Stdv	Post-op Mean and Stdv	p-value
AOP	74 ± 6	86.9 ± 6.4	0.0001
LAP	19.9 ± 5.4	13.6 ± 5.4	0.001
CVP	11 ± 6.4	13.7 ± 2.8	N.S.

Table 3.7. Physiologic Pressures (mmHg) Across Subjects

In general, over time renal function, as measured by creatinine, improved. Although total serum bilirubin levels increased post-operatively, over a one-month duration of reliable pump output, these values returned to normal.

All subjects experienced bleeding complications. Respiratory complications requiring ventilatory support during some portion of their recovery periods were administered to 11 of the 12 subjects. Eight subjects required dialysis due to renal dysfunction episodes, seven of whom resolved. For one subject, renal support was chronic both pre-operatively and post-operatively. Six subjects had post-operative hepatic failure, three of whom had pre-existing conditions. Support termination for

two of these three subjects was related to the hepatic condition. One subject with pre-existing condition recovered from his liver dysfunction. All three subjects without pre-existing conditions recovered from their respective hepatic episodes.

During the trial, the AbioCor ® demonstrated good performance. One subject developed extreme acidosis with pH<7 for a period of ~ 3 hrs during which the AbioCor ® continued to pump while the subject was treated with veno-veno Extra-Corporeal Membrane Oxygenation which reversed the hypoxic condition.

One subject developed malignant hyperthermia (106-107 °F) lasting for approximately 40 hrs. The AbioCor ® continued to perform while the subject's temperature was controlled by the use of dantrolene.

Additionally, the AbioCor ® functioned without compromise during extreme pulmonary hypertension. In at least one case, the Abiocor ® maintained 6-8 L/min of cardiac output despite having to pump against a pulmonary pressure of approximately 60 mmHg.

Under abnormal physiologic states such as extreme acidosis, hyperthermia, and elevated PAP, the system continued to perform while medical treatment was implemented to reverse the abnormality.

3.3.5 Safety and Probable Benefit

The results of the initial study of the AbioCor® provided the following safety data in subjects with severe end-stage heart failure facing imminent risk of death. Two device failures occurred, one anticipated and one unexpected, representing ~ 83% (10/12) failure-free device operation clinically consistent with the demonstrated one year bench operation. The observed stroke rate was 0.29 per subject-month. No device-related infection problems were observed in AbioCor® subjects. Safety features for power management have been built into the system to avoid unintentional misuses that may result in hazards.

The device restored normal hemodynamics and afforded dysfunctional end organs (e.g. kidney and liver), a chance of recovery. Although only two subjects were discharged from the hospital, one to home and the other to a hotel near the hospital, their experience showed that they and their caregivers managed the system outside of the hospital environment, in their home and community settings.

3.3.6 Quality of Life as Evidence of Probable Benefit

For subjects with no other treatment options, AbioCor® represents a potential benefit of additional time to live for an end-stage heart failure population.

Two subjects did not survive surgery and two others did not survive beyond 60 days. The ten subjects who survived the initial surgery and lived beyond 60 days experienced varying degrees of benefit. Four of the 10 patients had out-of-hospital

activities. The remaining 6 patients attained various levels of recovery including walking, ambulating regularly, and in-hospital excursions. All ten patients implanted with the AbioCor ® were able to interact with family members and were able to give and receive hugs, hold hands, smile and exchange conversation.

There was limited data on activity or QOL collected with objective and validated instruments. Nonetheless, the Minnesota Living with Heart Failure (MLWHF) tool was utilized to assess the subjects' quality of life. The MLWHF is based on perceived change relative to pre-implant assessment. Lower scores imply better QOL. However, several subjects were unwilling or unable to complete the questionnaire. Despite incomplete compliance, QOL information was gleaned from the available data. Figure 3.4 summarizes the MLWHF data. The pre-implant mean score was 80 ± 12 (n=13), while the post-implant mean score was 47 ± 23 (n=9). Typically, New York Heart Association (NYHA) Class IV patients have MLWHF scores in the 60's, while NYHA Class III patients are in the 50's. Seven of nine subjects with pre- and post-operative data showed QOL improvement at least one point in time.

In order to account for unanswered questions in the MLWHF questionnaire, pre- and post-operative questions that were answered were included in the analysis. Using this matching analysis, six subjects retained QOL data based on either their mean post-operative QOL or the last QOL prior to support termination. All nine subjects with post-operative QOL data had at least one QOL measured between one and three months. For the two subjects that lived beyond 6 months, the average intervals between QOL assessments were 2.1 months for one and 4.7 months for the other subject. For the 7 subjects that lived for less than 6 months, the mean duration between QOL assessments was 1.1 months. The interval between the last QOL assessment and termination of support was 1.1 months with the longest interval being 2.8 months.

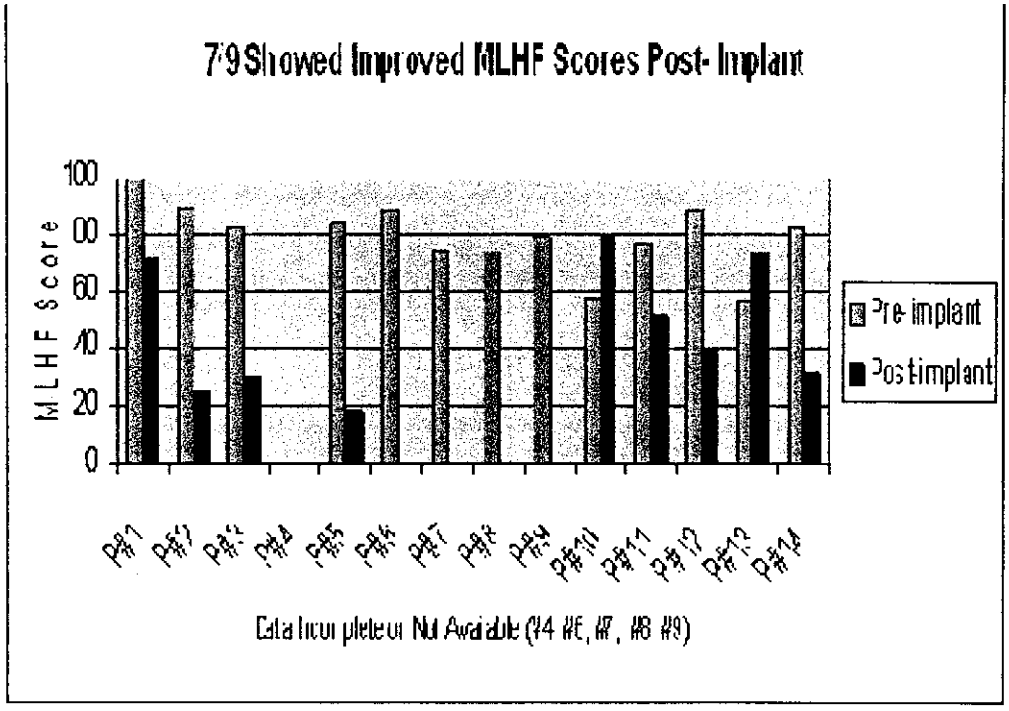


Figure 3.4. Pre- and post-implant MLHF Scores of AbioCor® subjects

Activity benefit was based on ambulation and in-hospital excursions. Interaction was based on the subject's ability to communicate with family members and friends post-implant.

3.4 Making the Decision

3.4.1 Informed Consent

If you pass the screening evaluations, members of the Medical Center's team, including your surgeons and others who will be involved in your care, and a patient advocate will take you through the Informed Consent process. A consent form will be reviewed with you and is intended to assist you in making an informed decision about whether to proceed with the AbioCor implantation. There is detailed information in the consent form reviewing what has been learned in the trial. Problems, difficulties, and events that you may experience after your implant and may lead to disabilities, pain, discomfit will be reviewed with you. Challenges and inconveniences living with the AbioCor will be explained to you. The need for family commitment will be emphasized. The need for you to participate and be part of a data collection system such that continued improvement in the care and management of AbioCor patients could occur will be explained to you.

3.4.2 End of Life Issues

The AbioCor is intended to provide life to those who have no other chance of survival. Some patients will recover from the procedure and live for some time. However, all recipients will likely die on the device. Since the AbioCor can continue to sustain the body's blood circulation indefinitely, the question arises as to when does life end? This question is similar to the situation where a patient on ventilatory support is comatosed. There will be circumstances in which either a recipient's mental capacity or their other organs are irreversibly compromised from various causes, such that circulation can be maintained while life may not exist. Such dilemmas can best be resolved with a pre-arranged medical power of attorney. You should also consider who your health care surrogate or medical power of attorney will be. This is a person you will be trusting to make decisions about you, for you, when you cannot. Patients should make clear to this person what his/her wishes are as to when and under what circumstances life-saving measures and AbioCor support should be stopped. Such a conversation should continue post implantation to minimize ambiguities and uncertainties in the final decision making process.

3.4.3 Potential Adverse Events

Based on the experience of the AbioCor initial clinical, the following adverse events can potentially happen to you when you are implanted with the AbioCor: strokes, bleeding, reoperation, infection, kidney failure, liver failure, breathing difficulties , device failure or sudden stoppage. Some of these complications may lead to your death.

3.4.4 Patient Advocate

A Patient Advocate is available to you at all times, if you desire, to help you understand the Informed Consent process, to answer any questions that you may have at any time during your AbioCor support period and to assist you with the challenges and risks of living and dying on the AbioCor.

4 System components

4.1 Implantable Kit

Item	Part #	Qty
Thoracic Unit	0034-6103	1
Implantable Battery	0034-3717	1
Implantable Controller	0034-3345	1
Implantable TET	0034-3213	1
Implantable Cable Harness	0034-3400	1
Model Kit		1
Implantable Battery Model	0034-4130	1
TET Implant Model	0034-4097	1
TU Inflow Fit Model	0034-4099	1
Thoracic Unit Implant Model	0034-4158	1
Controller/Battery Implant Model	0034-4098	1
Leak Checker	0034-1037	1
Low Position Graft	0034-1116	2
45 Degree Cuff w/ Stent	0034-1173	2
O-Ring	0034-8149	1
Signal Interface	0034-6046	1
Sterile Lubricant	0034-8154	1
Foley Catheter	5400-1008	2
Toomey Syringes	0034-1081	2
TET Pouch	0034-4129	1
Case	0034-8174	1
Case Diagram	0034-0966-00012	1
11' External TET -packaged	0034-4660	1
Clinician Manual	0034-0980-00022	1
Pre-Implant Check & Implant Procedures	0034-0980-00024	1

4.2 Console Kit

Item	Part #	Qty
AbioCor Console	0034-4430	1
Power Cord	6000-0025	1
Console case	0034-4400	1
RF Comm Module	0034-4458-HD	1
11' External TET packaged	0034-4660	1

4.3 PCE and Home Kit

Item	Part #	Qty
Packaged Hand Held Monitor	0034-4620	1
Handspring Visor Pro	2025-0015	1
Active Armor Case	0034-4674	1
RF Module	0034-4451	1
Shipping container		1
PCE Bag & TET driver, packaged	0034-4666	1
PCE Manual	0034-0980-00016	1
TET Driver		1
PCE Bag		1
Packaged PCE AC Converter USA	0034-4515	1
PCE Battery Packs	0034-4664	8
External Battery Charger	0034-4396-HD	1
5' External TET	0034-4668	2
Patient Manual	0034-0980-00011	1

5 Warnings

NOTE: A warning indicates a situation that could result in injury or death.

- The anticoagulation status of the patient should be closely monitored.
- Do **NOT** subject a patient who has been implanted with an AbioCor® System to Magnetic Resonance Imaging (MRI). The strong magnetic energy produced by an MRI machine can cause the AbioCor System components to stop working. An MRI can also damage the AbioCor System's electronics.
- Do **NOT** allow any metal objects within **3 inches** of the External Transcutaneous Energy Transmission coil (External TET) while it is connected to the Console or the PCE Module. Certain types of metal objects can quickly become extremely hot and present a burn or fire hazard.
- Do **NOT** place an External TET that is connected to the Console or the PCE Module within **3 inches** of a metal surface. The TET can become overheated, causing a fire hazard.
- Keep the External TET disconnected from the Console when it is not in use. This reduces the risk of creating a fire hazard and damaging the TET because of the TET accidentally being too close to a metal surface.
- The TET cable becomes warm during normal operation. If the cable becomes hot, replace the External TET. A hot cable may present a burn hazard.
- Do **NOT** administer cardiopulmonary resuscitation (CPR) to a person who has an AbioCor System. CPR will not work and may cause life-threatening bleeding.
- Many conditions that occur during the operation of the AbioCor System can trigger AbioCor System alarms. Do **NOT** operate the AbioCor System without training in how to handle these alarms. Injury or death may result if the alarms are not handled in a timely and appropriate manner.
- Do **NOT** allow a patient who has an AbioCor® System to travel to an altitude that is more than 2,500 feet higher or lower than the location at

which the AbioCor System was implanted. If emergency air transportation is needed, tell the pilot about the 2,500-foot restriction. Changes in air pressure caused by altitude changes may cause the AbioCor System to work incorrectly, resulting in injury or death.

- Do **NOT** submerge a patient who has an AbioCor System more than 2 feet below the surface of any body of water. The change in pressure that occurs underwater may cause the AbioCor System pressure measurements to be inaccurate and result in improper operation.

- Monitor the temperatures of the Implanted Controller, Implanted TET, and Implanted Battery by checking the Parameter Window, which is available at Show Param Window on the Main Menu. Patient complaints of a localized feeling of heat may indicate that one of these components is not operating properly or is operating outside of its intended range.

- Monitor the patient closely for signs of sepsis. Infections may make blood more prone to clotting, increasing the risk of cerebrovascular accident (CVA).

- Maintain a therapeutic level of anticoagulation to decrease the risk of thrombus formation.

- A person who has an AbioCor System must **NOT** do deep forward bends. These may cause discomfort or pain because of the rigid AbioCor components and may reduce blood flow resulting in low blood pressure, and fainting.

- When using an X-ray lead shielding apron, be sure to place a pad (such as Styrofoam® or towels) at least 3 inches thick between the External TET and the shielding apron. This prevents heating of the shielding apron.

- Do **NOT** use a Swan-Ganz® catheter or other catheters to measure blood pressure within the Thoracic Unit. Cardiac catheters can damage the blood-contacting surfaces in the Thoracic Unit and promote thrombus buildup.

- During clinical use, a spare AbioCor® Console or a PCE / Handheld monitor must be available at all times.

- Do **NOT** mask (disable) any alarms without **authorization**. Alarm masking can affect patient safety.

- Waveforms and values from patient monitoring equipment are intended only for data collection. Do **NOT** use this information for patient management.

- To prevent the risk of explosion, do **NOT** operate the Console near flammable anesthetics.

- To reduce the risk of electric shock, do **NOT** attempt to remove the Console housing or replace the Console Battery.

6 Cautions

NOTE: A caution indicates a situation in which equipment may malfunction, be damaged, or cease to operate.

- To prevent overheating and improper operation, do **NOT** block the AbioCor® Console cooling vents while the Console is operating. Blocked cooling vents can cause the Console to overheat and to work incorrectly.

- When using the Console on a soft or uneven surface, use the foldout stand to help maintain adequate clearance around the vents.

- Keep an External TET that is connected to the Console at least 1 foot away from any other External TET. TET electronics can be damaged if TETs are too close to each other.

- Do **NOT** clean the External TET, Radio Frequency (RF) Communications Module, or cables with disinfectants that contain oxidizers such as iodine (Betadine® or similar disinfectants), hydrogen peroxide, hypochlorite (chlorine bleach), permanganate, or chromate. These cleaners may break down the outer coverings of these components.

- Do **NOT** use cleaners that may stain the outer coverings of components and hide the breakdown of these coverings.

- Do **NOT** resterilize the External TET or cables. Additional sterilization can permanently damage these components.

- Do **NOT** allow any liquids (including water) to come in contact with any electrical connector pins. Contact with liquid can cause corrosion or electrical malfunction.

- When possible, maintain the data connection between the Console and ABIOMED. The information collected will assist clinicians in ensuring proper operation of the AbioCor® System and in analyzing alarms.

- Minimize exposure of AbioCor® System components to sources of electromagnetic interference (EMI). Exposure to sources of EMI, such as cell phones and two-way radios, may cause operational interference. To clear interference, either increase the distance between AbioCor System components and the EMI source or turn off the EMI source.

- Operation of AbioCor System components may interfere with the operation of other devices. If interference occurs, increase the distance between the device and AbioCor System components.

7 Reliability

Twenty-five implantable subsystems have been placed on reliability testing. Failure times ranged between 8.0 to 57 months. The average runtime time was 21.6 months (± 14.1). System reliability is determined to be greater than 80% at a confidence level of 80% for a one-year operation. Three major failure modes were observed: bearing, membrane wear, and fluid ingress. Two of the three failure modes have been observed clinically, a bearing failure at 5 months and a membrane wear at 17 months. Fluid ingress due to a breach of system hermiticity has not been encountered. A needle puncture of a cable sheath was encountered and the cable was surgically exchanged without patient compromise.

7.1 Safety Elements

Many safety elements are incorporated into the AbioCor system including:

- 24x7 clinical and technical support
- Complete backup system in each hospital
- Backup external PCEs and Handheld Monitors for home use
- Multiple alarm paths for low internal battery, low flow conditions
- TET self shut down under overload condition
- No skin penetration for external power transfer
- Internal battery capacity of greater than 30 minutes
- Continuous monitoring of the implantable system

8 Clinician Training Program

8.1 Outline

Training on implanting and care of the AbioCor patient will involve all members of the clinical team. This training includes didactic training, and/or animal lab training.

Clinical centers are expected to designate critical members of the AbioCor implant teams before AbioCor training can begin. Team members should include at least the following personnel:

Screening Team:
Heart failure cardiologist, Surgeon, Hematologist

Surgical Team: (minimum)
2 surgeons
First assistants
Scrub nurse
Circulating nurse
Perfusionist
Anesthesiologist
Device operator

Recovery team:
4 to 5 ICU recovery nurses, heart failure cardiologist, hematologist, infectious disease, neurologist, nutritionist, rehabilitation.

The AbioCor training program will consist of a minimum of two animal implant sessions combined with classroom instruction. The organization and timing of these training sessions will be arranged on a center by center basis.

8.2 Criteria for Clinical Readiness from Training Sessions

8.2.1 Successful completion of two animal implantations.

- Normal Post-implant hemodynamics must be demonstrated
- Demonstration of understanding of system electrical connections
- Demonstration of De-airing techniques

8.2.2 System Operator must demonstrate proficiency and knowledge by using the training loop.

8.2.3 Post-op team must understand device/physiologic interaction and patient management.

8.2.4 Clinical team must be familiar with patient selection criteria.

8.2.5 Clinical team must understand the anticoagulation management.

9 Implant Procedures

Standard operative aseptic techniques are followed.

9.1 Preparation

9.1.1 Perform Pre-Implant Check-Out of all AbioCor equipment.

9.1.2 Conduct AbioCor Console setup procedure

9.1.3 Perform Implanted System check-out in a sterile field

9.1.4 Conduct System Operation verification procedure

9.1.5 Perform TET and Charging System operational check

9.2 Implantation

A fully detailed implant procedure is described in the manual "Pre-Implant Equipment Check and Implant Procedures".

9.2.1 Using blunt dissection, form a pocket on the right side of the sternal incision site, in subclavicular tissue for the Implantable TET. Place the TET in the pocket. Tunnel the TET cable over the ribs and out through the sternotomy incision. Form abdominal pockets for the Implantable Controller (left) and

Implantable Battery (right) below the posterior sheath extraperitoneally.

9.2.2 Place the patient on full cardiopulmonary bypass (CPB). Remove the ventricles. Cut the tissue between the atria and ventricles leaving adequate left and right atrial tissue for attaching inflow cuffs.

9.2.3 Cut the tissue between the ventricles and the aorta and pulmonary artery (PA) distal to their respective valves. Trim or oversew excess tissue on the atrial appendages to prevent possible prolapse into the inflow valves.

9.2.4 Trim the left atrial cuff to the appropriate size. Then sew the cuff to the left atrial tissue and to a reinforcing layer of PTFE felt using a running polypropylene suture. Reinforce the anastomosis by sewing a second layer of felt around it. Sew off the coronary sinus and the PFO if one exists. Check the right and left atrial anastomosis for leaks using the leak checkers provided.

9.2.5 Trim the PA outflow graft to the appropriate length and sew to the PA using a running suture and a reinforcing layer of PTFE felt.

9.2.6 Trim the aortic outflow graft to the appropriate length and sew to the aorta using a running suture and a reinforcing layer of PTFE felt. Check the anastomosis for leaks using the leak checker without the Foley catheter.

9.3 Placing the Thoracic Unit

9.3.1 Fill the blood pumps with heparinized saline, and place the Thoracic Unit (TU) in the pericardial space.

9.3.2 Make the connections to the cuffs and grafts in the following order, left inflow cuff, PA graft, aortic graft and finally the right inflow cuff.

9.4 De-Airing and Start-up

9.4.1 Connect the yellow connector of the Implantable Cable to the yellow connector of the TU and tighten with the spanner wrench.

9.4.2 Attach Toomey syringe bodies to the side arms of the outflow grafts and place CPB suckers in the syringe bodies.

9.4.3 Release the caval tapes and allow the right atrium to fill. Partially occlude the venous return to the CPB machine.

9.4.4 Fill the TU by increasing central venous pressure (CVP) to 15 to 20 mmHg. Maintain CVP within this range during the de-airing procedure.

9.4.5 Begin with the low-flow Start Up states and quickly step through the first 3 states (if there are no filling problems).

9.4.6 When all air has been removed from the right blood pump, clamp the right side arm.

9.4.7 Inspect the left blood pump and valves for air. It will require increasing the beat rate to around 90 BPM to flush out all air bubbles. After satisfactory inspection, allow an additional 4 to 5 minutes to ensure that the left blood pump is de-aired.

9.4.8 During this de-airing time, blood is flowing from the right atrium through the AbioCor right pump, across the lung, returning to the left atrium into the AbioCor left pump, out the sidearm of the aortic graft. Blood captured by the Toomey syringe body is suctioned back to the cardiotomy reservoir. The CPB returns blood to the systemic circulation via the aortic cannula.

9.4.9 TEE should be used to verify that the left atrium is free of snow (microbubbles).

9.5 Transition from CPB to AbioCor

9.5.1 Reduce the TU beat rate to 60 bpm and CPB flow down to 1 liter per minute of flow.

9.5.2 Simultaneously clamp the left side arm and open the cross clamp. Do not allow the side arm and the cross clamp to be closed at the same time.

9.5.3 Closely monitor inflow pressures and compensate by making changes to volume and TU settings.

9.5.4 Discontinue CPB and reverse heparin.

9.5.5 Increase TU beat rate to desired blood flow, making sure that filling pressure remains between 15 and 20 mmHg.

9.6 Chest Closure

Baseline fit assessment of the AbioCor is essential to ensure the device can perform according to specifications. A major cause of performance problems is limited blood flow to the right or left ventricle. Every effort should be made to ensure there are no fit complications. The following recommendations are intended to help minimize this problem:

9.6.1 After the AbioCor is providing full support to the patient (and hemodynamics are stable with the chest open), baseline data should be collected:

- TEE should be recorded, showing acceptable pressure gradients (not exceeding twice normal) between the pulmonary veins and the left atrium.
- Hemodynamic parameters should be recorded, evaluating device output, central venous pressure, left atrial pressure, and aortic pressure.
- After the baseline fit assessment is complete, the chest should be approximated in the closed position. TEE and hemodynamic parameters should be reassessed and target pulmonary vein velocities of < 80 cm/second should be maintained.

9.6.2 Prior to chest closure, the chest cavity is washed liberally with a solution of Vancomycin (1 g/L), Amphotericin B (10 mg/L), 10% Betadyne solution in a 3:2:2 mixture to maintain aseptic condition.

10 Patient Management

The intent of postoperative management is to return the patient to normal hemodynamics and, ultimately, to return the patient to the home environment with good quality of life. Critical goals involved in this task include:

- Extubation
- Removing chest tubes, Foley catheters, and monitoring lines
- Controlling pain
- Recovering end-organ function
- Providing adequate nutrition
- Mobilizing as soon as possible

The following sections present an overview of the key aspects of management of a patient with an AbioCor System.

10.1 Volume / Fluid Management

The patient's fluid volumes can affect the operation of the AbioCor System, especially hypovolemia, which can cause inflow limiting manifested as inflow stenosis or occlusion. Volume management should include fluid intake and output measurements.

Volume and fluid management also includes assessment of the left and right hydraulic waveforms to evaluate the possibility of hypovolemia.

On the AbioCor System, hypovolemia manifests as right-side inflow limiting or simultaneous inflow limiting (on both the left and right sides), along with the resulting decrease in cardiac output. The filling pressures for each side, LAP and RAP (CVP), also decrease.

Hypovolemia can be caused by:

- Diuretic therapy
- Hemorrhage
- "Third space" fluid losses

When clinically prudent, inflow limiting due to hypovolemia should be treated by giving additional fluid volume, using blood products and albumin rather than crystalloid. If the patient cannot tolerate additional fluid volume, inflow limiting can be managed by changing the AbioCor System operating parameters.

10.2 Blood Pressure Management

Blood pressure management should aim to maintain pressures within standard physiologic ranges. The tools available to manage blood pressure include blood pressure medications, volume/fluid management, and AbioCor System parameter settings. The effects of parameter settings are summarized in the table below.

Effects of AbioCor System Parameter Settings on Blood Pressure

Setting	Effect on Blood Pressure
Beat rate	Increasing the beat rate decreases CVP, and increases AOP
Balance	Increasing the balance setting increases LAP and vice versa.
Motor speed	Under automatic control, motor speed increases as afterload pressures increase.

10.3 Anticoagulation Management

Anticoagulation management seeks to achieve and maintain normal hemostasis in the AbioCor patient to allow clot formation without producing inappropriate thrombosis. This requires balancing the clot-producing coagulation and platelet systems and the clot-dissolving fibrinolytic system. Although the AbioCor System is designed to minimize clot formation, implantation of the AbioCor System is likely to shift the balance toward clot formation and increase the likelihood of thrombosis. Anticoagulant and antiplatelet medications are used to shift the balance back.

This protocol entails using an individualized, multi-drug approach in conjunction with multi-system monitoring of the coagulation system. Primary monitoring tests and their recommended targets are shown on Table 10.1. Other tests that could provide further guidance include fibrinogen levels, Platelet Factor 4 and Beta Thromboglobulin levels. Table 10.2 lists the medications commonly used in hemostasis management for AbioCor patients.

Table 10.1 Primary Tests to Monitor Coagulation System and Suggested Targets

Target Variable	Range
Partial thromboplastin time (PTT)	2.0 to 2.5 times normal (45 to 55 sec)
International normalized ratio (INR)	2.5 to 3.5
Thromboelastography (TEG) [with and without heparinase, with platelet agonist]	Normocoagulable, coagulation index -2 to +1
Platelet Aggregation (ADP, Collagen, Epinephrine, Arachidonic Acid)	50% inhibition (Platelet Count 100,000- 300, 000) 70% inhibition (Platelet Count >300, 000)

Table 10.2 Medications Commonly Used for Hemostasis Management

Medication	Notes
Anticoagulants	
Heparin	Initial, short-duration therapy
Coumadin®	Longer term anticoagulant therapy
Platelet System	
Dipyridamole (Persantine®)	Platelet stabilization
Aspirin	Inhibits platelet aggregation
Ticlopidine (Ticlid®) or Clopidogrel (Plavix®)	For patients who cannot tolerate aspirin
Fibrinolytic System	
Aminocaproic acid (Amicar®)	Inhibits fibrinolysis
Aprotinin (Trasylol®)	Attenuates inflammation, fibrinolysis, and thrombin generation

Summary of Post-Operative Dosage and Monitoring Guidelines

Heparin therapy

- Initiated non-aggressively after surgical hemostasis has been verified and platelet count recovery is noted
  - chest tube drainage <30 cc/hr for between 24 and 48 hours.
  - should not initiate if platelet count < 100,000/µl, even in the absence of bleeding, unless there are signs of platelet count recovery.
- Recommended starting dose is 2-5 Units/kg/hr, less if patient is cachectic.
- Recommended target: 2.0 to 2.5 times normal (45-55 sec).
- Dosage should however, be titrated to achieve normocoagulability by TEGs without heparinase.

Warfarin therapy

- Initiated when renal and hepatic functions improve, prealbumin levels increase and nutritional status becomes stable.
- Recommended starting dose is 2.5 to 7.5 mg/day; specific dosage governed by body mass, vitamin K intake, nutritional state and drug interaction potential.
- The target INR should be between 2.5 to 3.5.
- TEGs with heparinase should be used to detect normocoagulability for further guidance.
- During conversion, while warfarin is taking effect,
    - heparin should be titrated down, guided by TEGs without heparinase.
    - Heparin is discontinued when TEGs with heparinase are normocoagulable for 2 consecutive days, indicating that the warfarin effect has taken hold.

Antiplatelet therapy

- Initiated when there is no evidence of bleeding and platelet count is satisfactory (>100,000 per µl).
- Asprin, 81 – 325 mg/day
    - Plavix, 75 mg/day if aspirin is not tolerated
- Dipyridamole, 75-100mg Q8 initially.
    - Increase by 75-100mg Q6-Q8 per 100, 000 platelet count increase.
    - Not to exceed 300mg Q6 or 450mg Q8.
    - May be guided by Platelet Factor 4 and Beta Thromboglobulin levels.
- Weekly platelet aggregation tests should be used to titrate dosages for platelet inhibition (see Table 10.1).
- Weekly regular TEGs (target MA=60-65) and TEGs with platelet agonist should be used for platelet function assessment.

We recommend being conservative when making changes, ≤ 50%, to avoid large swings in coagulation function and test results.

10.4 Infection Management

Antibiotic therapy should be provided prophylactically from the recovery to the step-down phases of AbioCor support. Longer duration and/or organism specific medication administration is at the discretion of the clinician.

To minimize the chance of infection, indwelling lines should be discontinued as soon as possible. The Millar left atrial line may be left for longer periods of time at the discretion of the physician. All discontinued line tips should be sent for routine culture.

The patient will have at minimum the following incisions and line insertion sites cultured:

- median sternotomy,
- chest tube,
- central line,
- radial or femoral arterial line insertion sites.

An antifungal agent should be administered for 5 to 7 days as well as vancomycin until all drains are removed. Strict aseptic technique should be used for all dressing changes. Dressing changes should be done according to ICU policy and protocol, or per the physician's orders.

Nutrition is a major factor in preventing infection (see following section). Infection should be suspected if any of the following occurs: WBC increase, temperature increase, positive cultures, infiltrate on x-ray, skin redness, pain/tenderness and any significant decrease in blood pressure with no change in device output.

10.5 Nutritional Management

Patients who qualify for the AbioCor are those who have had extended durations of congestive heart failure (CHF), may be elderly and are likely to be cachetic. A nutritional support team, consisting of a registered dietician, pharmacist, and a physician should evaluate a patient's needs. It is important that a full plan for a patient is in place to support recovery. The following guidelines are provided to optimize patient recovery.

10.5.1 Pre-operative management

- Obtain baseline labs to evaluate nutritional status – albumin, pre-albumin, transferrin levels, resting energy expenditure, etc.
- Obtain Registered Dietician consult – evaluate history, dietary intake, degree of malnutrition, GI function/symptoms, nutritonal needs, etc.
- Provide patient-specific diet and nutritional supplements to optimize pre-op status
- Consider ACE Inhibitor, beta blocker to reduce further CHF-related cachexia risks

10.5.2 Post Operative management

- Correct all volume and electrolyte disorders prior to nutrition support
    - Correct vitamin and trace-element deficiencies as well, e.g. 50-250 mg thiamine.
- Initiate total parenteral nutrition (TPN) within 24-48 hours post implant to promote anabolic state.
- When bowel sounds return, enteral nutrition support (naso or jejunostomy tube) may be initiated.

  - Initiate with caution as a chronic poorly perfused gastrointestinal (GI) tract may be susceptible to ischemic injury with enteral nutrition
  - Start at 10 to 15 ml/hr and advance to 50% of resting energy expenditure as tolerated by GI tract. If not tolerated, evaluate for TPN.
  - Use formulas containing fiber if colon is working, otherwise, use semi-elemental formulas
  - Use a semi-recumbent position for enteral feeding to reduce aspiration risks
  - Assess for diarrhea and abdominal distention
- When the patient is extubated, initiate patient-specific diet
  - small frequent meals are better tolerated
  - caloric intake should normally start with 10-15 Kcal/kg/day, protein administration: 0.8-1 gm/kg/day and advance to no more than twice these values as the patient improves.
  - Carbohydrate should be started at 2 to 3 gm/Kg/day and increased while glycemic control is maintained.
  - Lipid administration should be maintained at approximately 15% of the caloric intake.
- Regardless of intake method, closely monitor blood glucose (target 80-110 mg/dl) and metabolic parameters (eg. K^+, Mg^{2+}, phosphorus, Na^+, acid-base balance, osmolality, etc.)
- Prealbumin levels will be checked once a week to adjust protein supplement needs.

10.5.3 Complications and other Considerations

- Renal Failure
  - Patients on hemodialysis require 20-100% higher nutrition/protein needs.
- Low oral intake
  - Use appetite stimulants such as megestrol acetate (Megace™) and methylphenidate (Ritalin™) for depressed patients.
- Gastroparesis
  - Use promotility agents such as metoclopramide (Reglan™).
- Diarrhea
  - Avoid holding feeding for diarrhea. Include fiber. Check for C difficile.
- Anemia and iron deficiency
  - Avoid IV iron replacement in critically ill or infected patient. Supplement iron only as patient stabilizes. Consider epoetin alpha.
- Consider prophylactic use of proton pump inhibitors (eg. Omeprazole, Pantoprazole, etc).
- Perform caloric count over three consecutive days to assess adequate intake

An ongoing program of observation, evaluation and testing should be implemented to detect complications and monitor progression of patient nutritional status.

10.6 Rehabilitation

A regimented rehabilitation program is an integral part of nurturing a patient back to recovery from both the implant procedure and patient's pre-existing debilitated condition due to years of living with cardiac failure. For an AbioCor recipient, recovery consists of three stages, bed exercises, walking, and supervised exercises. While recovering in bed, nonresistive motions of extremities should be encouraged and would be well tolerated without stress to the sternal incision. Walking should start slowly with supervision and gradually increase to 10 minutes as the patient could sustain such effort. Beyond walking, non-impact exercises should be preferred for musculoskeletal reconditioning, such as stationary cycling. The patient could be exercising either with the PCE deriving power from the external battery or without this source while on internal battery. The external system should be constantly monitoring the AbioCor during such exercises.

10.7 Patient Discharge

10.7.1 Overview of the discharge process

To ensure the safety of the patient, primary home caregivers (and if possible, the patient) must:

- Complete the Home User Training Program and demonstrate the ability to operate and troubleshoot the AbioCor System.
- Demonstrate knowledge of the appropriate responses to possible emergencies.
- Possesses the required emergency and back-up information, equipment, and accessories.

When the patient is stable, meets certain clinical status requirements, and the patient or family member is capable of taking charge of the care plan, discharge to an "intermediate" facility near the hospital can be considered. If the opinion of the clinical team is that the patient and family support group has demonstrated their ability to care for the patient and the AbioCor System, the patient can be discharged to home.

Preparation for discharge is an ongoing activity. It should begin when the patient is transferred out of the ICU. The process should involve the patient and the patient's primary home caregivers. The discharge plan is developed around restoring the patient's physical condition to a point where they can participate in there own care. A transition in the care of the patient and the operation of the AbioCor System from the hospital staff to the home caregivers occurs. The typical sequence of events leading to discharge would include:

1. Increasing physical activity in the step-down unit including:
   - Patient transferring from bed to chair without assistance
   - Patient able to care for personal hygiene

2. In-hospital excursions, for example:
   - To the hospital cafeteria
   - To outside areas such as roof decks and gardens.

3. Out-of-hospital excursions, for example:
   - Local restaurants and parks
   - Shopping Malls

4. Day trips to Intermediate Care Facility such as a local hotel or apartments close to the medical center.

5. Overnight stays at the Intermediate Care Facility.

6. Discharge to home

10.7.2 Home User Training Program

The transition to home living with the AbioCor involves careful preparation and assessment of the patient, the caregivers, and the patient's home environment and support structure. Patient and caregiver training are essential for a safe and successful discharge experience. Before discharge from the hospital, the AbioCor patient and their respective caregivers will be trained by the AbioCor Center's staff. The center's device coordinator is the key person conducting such training. ABIOMED will provide support and call availability on a 24/7 basis.

Proficiency on each training requirement listed below will be based on observational testing. The AbioCor patient and their respective caregivers should be capable of operating the AbioCor system and feel completely comfortable in their ability to address and respond to each function defined in the training requirements of the AbioCor system.

The Trainer will document each training requirement when addressed and proficiency is established.

- Identify the AbioCor System components and functions
- Understand and identify the AbioCor console controls and indicators.
- Use the AbioCor controls in Home Operating Mode
- Understand and respond appropriately to AbioCor Console alarms
- Understand and use of the External Transcutaneous Energy Transmission coil (External TET)
- Understand and establish RF communications
- Understand and use the Patient Carried Electronics (PCE)
- Understand emergency procedures
- Understand and demonstrate the importance of their medications and self care.

10.7.3 Local Services Readiness

There are no special requirements in the power needs for the home or the work environment. The Local Power Company will be notified of the fact that there is a customer that requires power for life support equipment and that restoration of power to the recipient's home in the event of power outage is a priority.

The local Emergency Medical Services (EMS) will be informed about the AbioCor patient. Emergency Medical Technicians will be trained on what procedures can be performed, such as respiratory support, and those that should be avoided, such as the use of a defibrillator. A local EMS will be trained on the emergency response protocol in the event the patient requires transport to the implant center for additional care. This will include flight transport altitude limits if that is the mode to be used.

A family physician associated with a community hospital and a select staff from the hospital will be trained on basic care for the patient. This may include basic anticoagulation monitoring using INR measurement, continued physical therapy, and etc. The patient will return to the implant center for regular checkups scheduled by the device coordinator or in case of an emergency.

10.7.4 Post discharge monitoring

10.7.4.1 Plan of Care

Each AbioCor patient will be given a plan of care designed for that patient. The plan will be reviewed with the patient and the family by the clinical team. With each office visit, progress will be compared with the plan, and the plan will be modified as needed.

10.7.4.2 AbioCor Log sheet

The patient or their caregiver will fill out the AbioCor flow sheet at a minimum of two times a day.

10.7.4.3 Medication log

A log listing all of the AbioCor patient's medication will be reviewed with the patient and caregivers.

10.7.4.4 Appointment calendar

The coordinator will develop a calendar listing regularly scheduled appointments.

10.7.4.5 Journal

AbioCor patients will be encouraged to keep a journal where they can make notes regarding any problems with the implants or external equipment. They will also be encouraged to make notes about their overall health or any other issues they may be feeling.

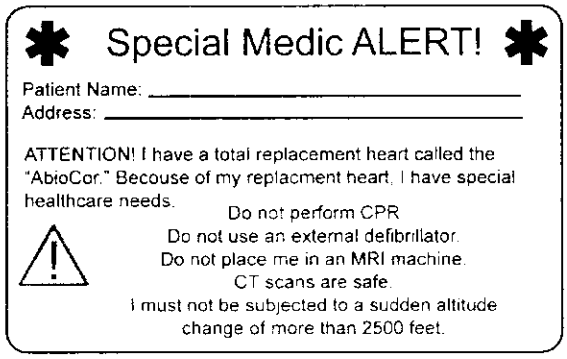
10.7.4.6 Hospital maintained Records

- Patient demographics
- List of consults
- Equipment logs
- Medication logs
- Laboratory blood work tracking sheet.

10.7.4.7 Contact information

Each AbioCor patient will be provided with an ID card with brief emergency medical instructions and a contact list.

Front



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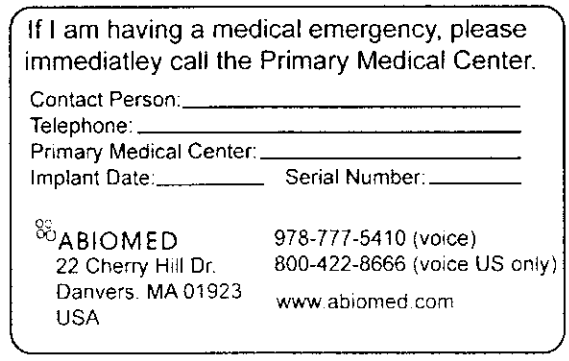

11 Overview of Manuals

11.1 Clinician Manual

This Clinician Manual is designed for experienced healthcare professionals responsible for patients implanted with an AbioCor Implantable Replacement Heart System (AbioCor System). This manual contains clinical and technical considerations to guide care for these patients. Clinicians should have extensive experience in the care and management of postoperative cardiac surgical patients including those requiring mechanical circulatory assist devices.

Information and instructions given in this manual are not intended to supersede established medical procedures concerning patient care. Best practice, as determined by the medical community, should always be observed. In each case, the clinician must determine whether the application of information provided is appropriate for the particular clinical setting.

This manual should be used to support patients before and after implantation. For information on implantation (including replacement of implanted components), refer to the *AbioCor Pre-Implant Equipment Check and Implant Procedures*.

11.1.1 Manual Overview

This Clinician Manual provides Instructions For Use for the AbioCor Implantable Replacement Heart System. This manual also includes important information concerning patient monitoring. The following summarizes the contents of each section of this manual:

- **Section 1 (Warnings and Precautions)** discusses the warnings and precautions pertaining to the use of the AbioCor System.
- **Section 2 (Indications and Potential Adverse Events)** discusses indications for use of the AbioCor System and potential adverse events that may be associated with its use.
- **Section 3 (The AbioCor System)** provides an overview of the AbioCor System and describes the system's major Implanted and External components.
- **Section 4 (Using the AbioCor Console)** describes the procedures for setting up and operating the AbioCor Console.

- **Section 5 (Using the Console in Clinical Mode)** describes where to find information available in the Clinical Mode and how to use and navigate through the Clinical Mode windows and popup dialogues.

- **Section 6 (Managing an Implanted AbioCor System)** presents the information on power management, TET management, communications management, and hemodynamic management to aid in managing an AbioCor System that has been implanted in a patient.

- **Section 7 (Caring for a Patient with an Implanted AbioCor System)** describes considerations and procedures for the care of patients with implanted AbioCor Systems.

- **Section 8 (Transitioning the AbioCor Patient to Home Living)** describes discharge planning and procedures, including home caregiver and patient training requirements.

- **Section 9 (Alarms)** describes the AbioCor alarm and warning system.

11.2 AbioCor Pre-Implant Equipment Check and Implant Procedures

This manual is designed for the medical professionals involved with the surgical implantation of the AbioCor Implantable Replacement Heart System. It contains detailed instructions to be followed prior and during the implantation of the AbioCor System. Instructions are also provided for the surgical replacement of individual or combinations of Implanted System components.

11.2.1 Manual Overview

- **Section 1 (Warnings and Cautions)** discusses the warnings and precautions pertaining to the use of the AbioCor System and the implant procedure.

- **Section 2 (Pre-Implant Equipment Check)** details the procedures to check the performance and condition of the equipment used for implantation

- **Section 3 (Implant Procedure**) details the procedures to implant the AbioCor Implantable Replacement Heart System.

- **Section 4 (Replacing Implanted System Components)** details procedures to replace Implanted System components.

When implanting the AbioCor System, use this manual in conjunction with the *AbioCor® Clinician Manual.*

These instructions are not intended to substitute for the independent medical judgment of each medical professional.

11.3 Patient Manual

The patient manual will help the patient and caregiver understand how to live comfortably with the AbioCor Replacement Heart. The manual includes information about how the AbioCor System works in the body and how it fits into the patient's daily routine. The manual also instructs users on how to adjust the system and when to call the doctor or the clinic.

11.3.1 Manual Overview

- **Section 1** lists important warnings and precautions to avoid potential safety problems and ensure the best results from the AbioCor System.
- **Section 2** describes the parts of the AbioCor System and how they work together to keep blood flowing normally.
- **Section 3** provides recommendations on daily living situations with the AbioCor Replacement Heart. It provides guidelines on nutrition, sleep, exercise, shower, travel, and the maintenance of other daily routines.
- **Section 4** describes how to connect and operate the external controls of the AbioCor System, i.e. using the Console.
- **Section 5** describes how to transfer control from the AbioCor Console to the Patient-Carried Electronics unit when more freedom of movement is desired.
- **Section 6** provides an overview of the AbioCor alarms.

11.4 Patient-Carried Electronics

The Patient Carried Electronics (PCE) manual provides information to help the patient and caregiver understand how to use the PCE and Hand Held Alarm Monitor safely and comfortably.

11.4.1 Manual Overview

- **Section 1 (Warnings and Precautions)** lists important precautions to avoid potential safety problems.
- **Section 2 (PCE Overview)** describes the function of the Patient-Carried Electronics (PCE).

- **Section 3 (Basic PCE Operation)** shows how to use the PCE and how to charge/replace batteries. It also shows how to keep the unit clean.

- **Section 4 (Transferring Support Between the Console and PCE)** describes how to transfer support from the AbioCor Console to the PCE when the patient wants to be away from the Console, and how to transfer support from the PCE back to the Console.

- **Section 5 (PCE Alarms)** describes the alarms potentially seen and heard when using the PCE.

11.5 AbioCor Quick Guide

The Quick Guide is intended to be used by patients and caregivers. It is designed to provide easy-to-access information about AbioCor Console and Patient-Carried Electronics (PCE) layout. It also provides information for making adjustments and handling alarms.

This information does not replace the Patient Manual or PCE Instructions for Use. Instead, it is intended to provide reminders about ***selected*** key aspects of the Console and the PCE.

Appendix A – Criteria for Biventricular Failure

The determination of chronic biventricular failure will be based on meeting the following conditions on both sides of the heart:

Left sided failure
Elevated left atrial pressure (≥ 18 mmHg), low cardiac index (≤ 2.2 L/min), and low LVEF (≤ 20%), or CT/MRI evidence of distended left atrium (left atrial volume index ≥ 70 cc/M^2).

Right sided failure
Elevated right atrial pressure (≥ 20 mmHg) with evidence of peripheral congestion, or evidence of hepatic congestion of cardiac origin with a total bilirubin between 1.5 and 3.5 mg/dL, or CT/MRI evidence of distended right atrium (right atrial volume index ≥ 70 cc/M^2).

Left sided pressures may be lowered by vasodilators, inotropes or blockers of the renin-angiotensin system, such as ACE inihibitors or AII receptor blockers. Persistent elevation of right sided pressure (right atrial pressure) even in the presence of lower left sided pressure (left atrial pressure or wedge pressure) is usually indicative of right sided failure. The parameters listed above imply optimal medical management including inotropes and/or vasodilators that have failed to improve the clinical picture.

Based on all the available patient data and the criteria described above, a heart failure cardiologist will be the final sign off that the patient under consideration is in biventricular failure and that the inclusion and exclusion criteria are met.

AbioCor®

Implantable Replacement Heart System

CLINICIAN MANUAL

ABIOMED®

AbioCor®

Implantable Replacement Heart System

CLINICIAN MANUAL

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July 2004
Document No. 0034-0980-00010 Rev. 1

Humanitarian Device. Authorized by Federal law for use in the treatment of patients with irreparably damaged hearts, at imminent risk of death with no other treatment options. The effectiveness of this device for this use has not been demonstrated.

IMPORTANT NOTICE: Read this ***entire*** manual before using the AbioCor Implantable Replacement Heart (AbioCor). The AbioCor is to be used only in accordance with this manual.

Information contained in this document is subject to change without notice.

Contents

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Introduction

Purpose of manual

This Clinician Manual is designed for experienced health care professionals responsible for patients implanted with an AbioCor Implantable Replacement Heart. This manual contains clinical and technical considerations to guide care for these patients. Clinicians should have extensive experience in the care and management of postoperative cardiac surgical patients including those requiring mechanical circulatory assist devices.

Information and instructions given in this manual are not intended to supersede established medical procedures concerning patient care. Best practice, as determined by the medical community, should always be observed. In each case, the clinician must determine whether the application of information provided is appropriate for the particular clinical setting.

This manual does not include information on implantation. It should be used to support patients before and after implantation.

Manual overview

This Clinician Manual provides instructions for use of the AbioCor Implantable Replacement Heart System. This manual also includes important information concerning patient monitoring. The following summarizes the contents of each section of this manual:

- **Section 1 (Warnings and Precautions)** discusses the warnings and precautions pertaining to the use of the AbioCor System.
- **Section 2 (Indications and Potential Adverse Events)** discusses indications for use of the AbioCor System and potential adverse events that may be associated with it.
- **Section 3 (The AbioCor System)** provides an overview of the AbioCor System and describes the system's major internal (implanted) and external components.
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- **Section 7 (Caring for a Patient with an Implanted AbioCor System)** describes considerations and procedures for caring for patients with implanted AbioCor Systems.

- **Section 8 (Transitioning the AbioCor Patient to Home Living)** describes discharge planning and procedures.

- **Section 9 (Alarms)** describes the AbioCor alarm and warning system.

1 Warnings and Precautions

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Warnings

Note: A warning indicates a situation that could result in injury or death.

Do *NOT* subject a patient who has been implanted with an AbioCor Implantable Replacement Heart System to Magnetic Resonance Imaging (MRI).

The strong magnetic energy produced by an MRI machine may cause the AbioCor System components to stop working. An MRI may also damage the AbioCor System's electronics.

Do *NOT* allow any metal objects within *3 inches* of the External Transcutaneous Energy Transfer coil (TET) while it is powered. Certain types of metal objects may quickly become extremely hot and present a burn or fire hazard.

Do *NOT* place a powered TET (connected to the Console or PCE) on a metal surface.

Doing so will cause the TET and the metal surface to become hot. This could create a fire hazard and could also damage the TET.

Do *NOT* administer CPR to a patient who has been implanted with an AbioCor System.

CPR does not work with an AbioCor Replacement Heart, and may cause life-threatening bleeding.

Many conditions that occur during the operation of the AbioCor System trigger AbioCor System alarms. Any person operating the AbioCor System must be knowledgeable in understanding and reacting to these alarms.

Death or serious injury may result if the alarms are not handled in a timely and appropriate manner.

Do *NOT* allow a patient who has been implanted with an AbioCor System to travel to an altitude that is 2,500 feet higher than the site at which the implant was performed.

Travel in an airplane is *NOT* permitted.

If emergency transport is required, air medical transport via helicopter is permitted, subject to the change-in-altitude restriction noted above.

To prevent corrosion or electrical malfunction, do *NOT* allow any contaminating material, saline, blood products, etc, to contact any electrical connectors or connector pins that are part of the AbioCor System.

During clinical use, a spare Console unit should be available at all times.

Only *authorized* users are permitted to change Console alarm properties.

To prevent the risk of explosion, do *NOT* operate the AbioCor Console near flammable anesthetics.

To reduce the risk of electric shock, do *NOT* attempt to remove the Console housing or replace the Console battery pack.

Precautions

Note: A precaution indicates a situation in which equipment may malfunction or be damaged.

To prevent overheating and improper operation, do *NOT* block the Console cooling vents while the Console is operating.

Blocked cooling vents may cause the Console to overheat and to work incorrectly.

When using the Console on a soft or uneven surface, *use the foldout stand* to help maintain adequate clearance around the vents.

To prevent damage to TET driver circuitry, be sure to maintain a distance of at least 1 foot between a powered External TET and any other External TET (e.g., a spare TET).

Disconnect the External TET from the Console when not in use [e.g., when the patient is using the Patient-Carried Electronics (PCE)].

Do *NOT* expose the External TET, RF Communication Module, or cables to disinfectants that contain oxidizing agents such as iodine (e.g., Betadine®), hydrogen peroxide, hypochlorite, permanganate, and chromate.

Such exposure may damage the outer coverings of these components and may adversely affect component life, the mechanical or flex properties of these components, and the ability of these components to exclude moisture.

Do *NOT* expose the External TET, RF Communication Module, or cables to disinfectants that are highly colored or staining (e.g., Betadine).

Clinicians need to be able to see and assess damage or deterioration in these components. Stains or discoloration can interfere with this assessment.

Do *NOT* re-sterilize the External TET or cables.

Sterilization may permanently damage these components.

To prevent possible damage to the Implanted controller, the Console Operator must confirm that the implanted system voltage does not exceed 40 volts.

The implanted system voltage is shown in the TET Alignment window in the upper right corner of the Monitor and Implant mode screens.

2 Indications, Contraindications and Potential Adverse Events

Contents

Overview

The AbioCor System is designed for use by patients who have irreparably damaged hearts or who are at risk of imminent death as a result of end-stage heart failure that cannot be treated by optimal medical treatment. Patients who are candidates for the AbioCor System have biventricular failure but typically have other vital organs that continue to be viable or are recoverable.

Indications and Contraindications

Indications

The AbioCor® is indicated for use in severe biventricular end stage heart disease patients who are not cardiac transplant candidates and who

- are less than 75 years old,
- require multiple inotropic support,
- are not treatable by LVAD destination therapy,
- are not weanable from biventricular support if on such support.

The determination of chronic biventricular failure will be based on meeting the following conditions on both sides of the heart:

Left sided failure
Elevated left atrial pressure (= 18 mmHg), low cardiac index (≤ 2.2 L/min), and low LVEF (≤ 20%), or CT/MRI evidence of distended left atrium (left atrial volume index = 70 cc/M^2).

Right sided failure
Elevated right atrial pressure (= 20 mmHg) with evidence of peripheral congestion, or evidence of hepatic congestion of cardiac origin with a total bilirubin between 1.5 and 3.5 mg/dL, or CT/MRI evidence of distended right atrium (right atrial volume index = 70 cc/M^2).

Left sided pressures may be lowered by vasodilators, inotropes or blockers of the renin-angiotensin system, such as ACE inihibitors or AII receptor blockers. Persistent elevation of right sided pressure (right atrial pressure) even in the presence of lower left sided pressure (left atrial pressure or wedge pressure) is usually indicative of right sided failure. The parameters listed above imply optimal medical management including inotropes and/or vasodilators that have failed to improve the clinical picture.

Contraindications

The AbioCor should not be used in patients:

- who has irreversible failure of any other internal organ (eg. kidney, liver, etc) besides their hearts
- who do not have adequate family or psychosocial support
- whose preoperative noninvasive anatomical assessment indicates inadequate fit and that the thoracic volume is unable to accommodate the device
- who has any kind of bleeding or blood clotting disorder

Based on all the available patient data and the criteria described above, a heart failure cardiologist will be the final sign off that the patient under consideration is in biventricular failure and that the inclusion and exclusion criteria are met.

Potential Adverse Events

Surgery to implant an AbioCor Implantable Replacement Heart, and use of the AbioCor System, are associated with a variety of potential complications. Most of the complications that may occur with the AbioCor System are similar to those associated with other major cardiac surgery such as a heart transplant or ventricular assist device (VAD) implantation.

Based on the experience of the AbioCor initial clinical trial, the following complications and adverse events can potentially occur in patients implanted with the AbioCor:

- Bleeding events may occur that require additional surgery, procedures or blood transfusions
- Surgery is required if your internal battery or TET needs replacement
- Infection may be a complication during your recovery period in the hospital
- Kidney, liver, and lung complications may occur and thus may necessitate treatments to reverse
- Recovery can be extended in duration and may lead to depression and other psychiatric episodes
- An extended recovery period may necessitate the use of feeding tubes or other means of ensuring adequate nutrition
- Strokes may occur that could result in incapacitation and death
- Device may stop suddenly leading to death

3 The AbioCor System

Contents

Overview

The AbioCor System is intended to replace the patient's natural heart. It is designed for patients whose hearts are irreparably damaged or who are at imminent risk of death by heart failure but have other vital organs that are viable.

An implanted, working AbioCor System includes 5 implanted components (see Figure 3.1 and Table 3.1) along with external components (see Table 3.2) that control and power the implanted components.

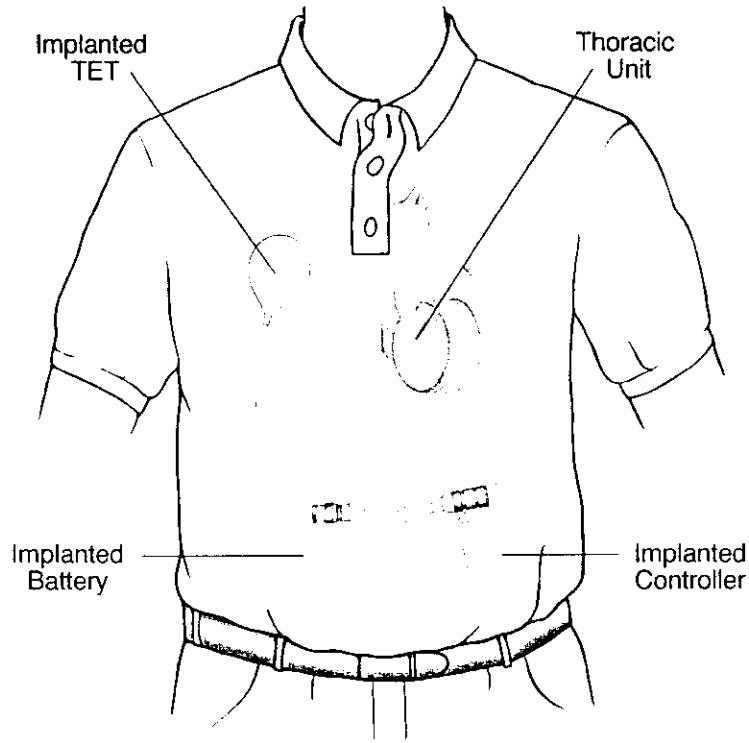


Figure 3.1 AbioCor Implanted Components

The internal (implanted) components receive power and control signals from either the AbioCor Console or the Patient-Carried Electronics (PCE). The AbioCor Console is the primary interface and power source for the implanted components. The PCE is a more portable system designed to allow independent mobility. The PCE is briefly discussed in Appendix A and more fully discussed in a separate Patient-Carried Electronics (PCE) manual.

Table 3.1 Primary Implanted Components of the AbioCor System

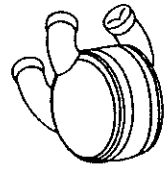
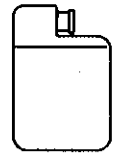
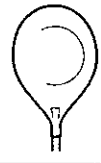
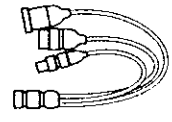
Component		Function
Thoracic Unit		Pumps blood
Implanted Controller		Controls the pump
Implanted Battery		Backup internal power
Implanted TET (Transcutaneous Energy Transfer)		Receiver for external power
Implanted Cable		Connects the internal components

Table 3.2 Primary External Components of the AbioCor System

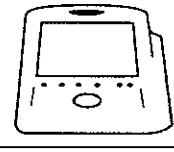
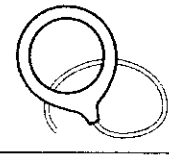
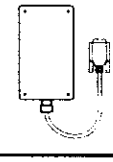
Component		Function
Console		Shows and controls system status and settings
External TET (Transcutaneous Energy Transfer)		Transmitter for external power
RF (Radio Frequency) Communication Module		Communicates with the Implanted Controller

Figure 3.2 illustrates the relationships among the internal and external AbioCor System components.

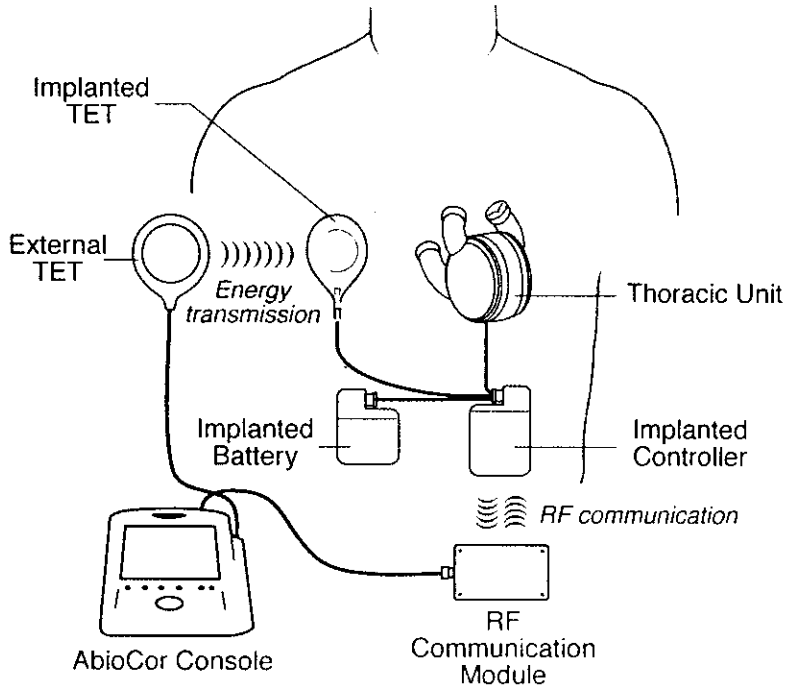


Figure 3.2 The AbioCor System

Thoracic Unit

Overview

The Thoracic Unit is the pump that replaces the ventricles of the natural heart. It is the largest and most complex component of the AbioCor System.

The primary components of the Thoracic Unit, shown in Figure 3.3, are the:

- Energy Converter
- Right blood pump
- Left blood pump

This section describes these components in detail.

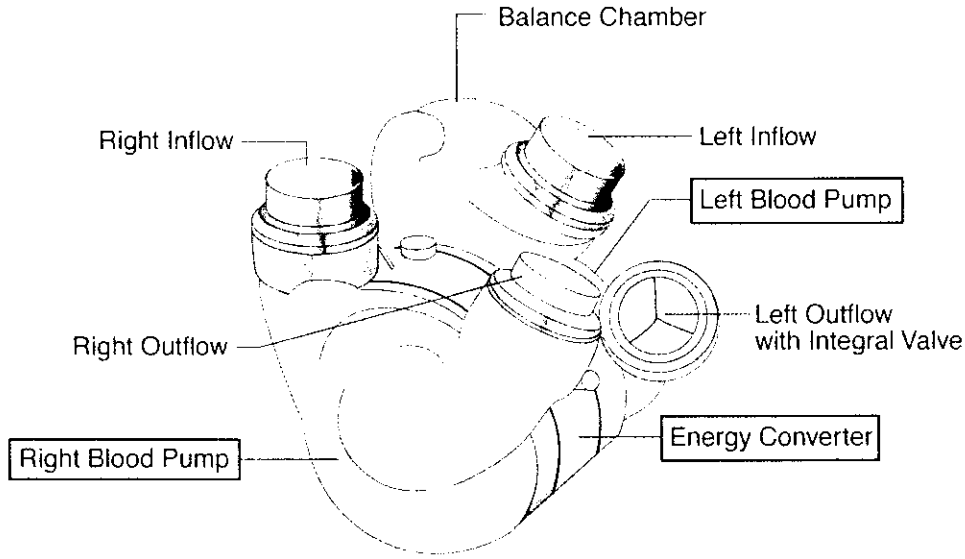


Figure 3.3 AbioCor Thoracic Unit

Figure 3.4 shows a simplified view of the Thoracic Unit's operation. The Thoracic Unit consists of two blood pumps sealed to and separated by the Energy Converter. Each blood pump can be seen as a hard-shelled chamber containing a balloon filled with blood. The space between the balloon and the Energy Converter is filled with hydraulic fluid. The Energy Converter moves hydraulic fluid from one side to the other, squeezing the balloon in one pump and forcing blood out of it. Simultaneously, blood is actively drawn into the other pump, filling it for the next cycle. The Energy Converter pumps hydraulic fluid in each direction alternately so that the left and the right blood pumps alternately

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eject blood. The Thoracic Unit's operation is described in more detail later in this section.

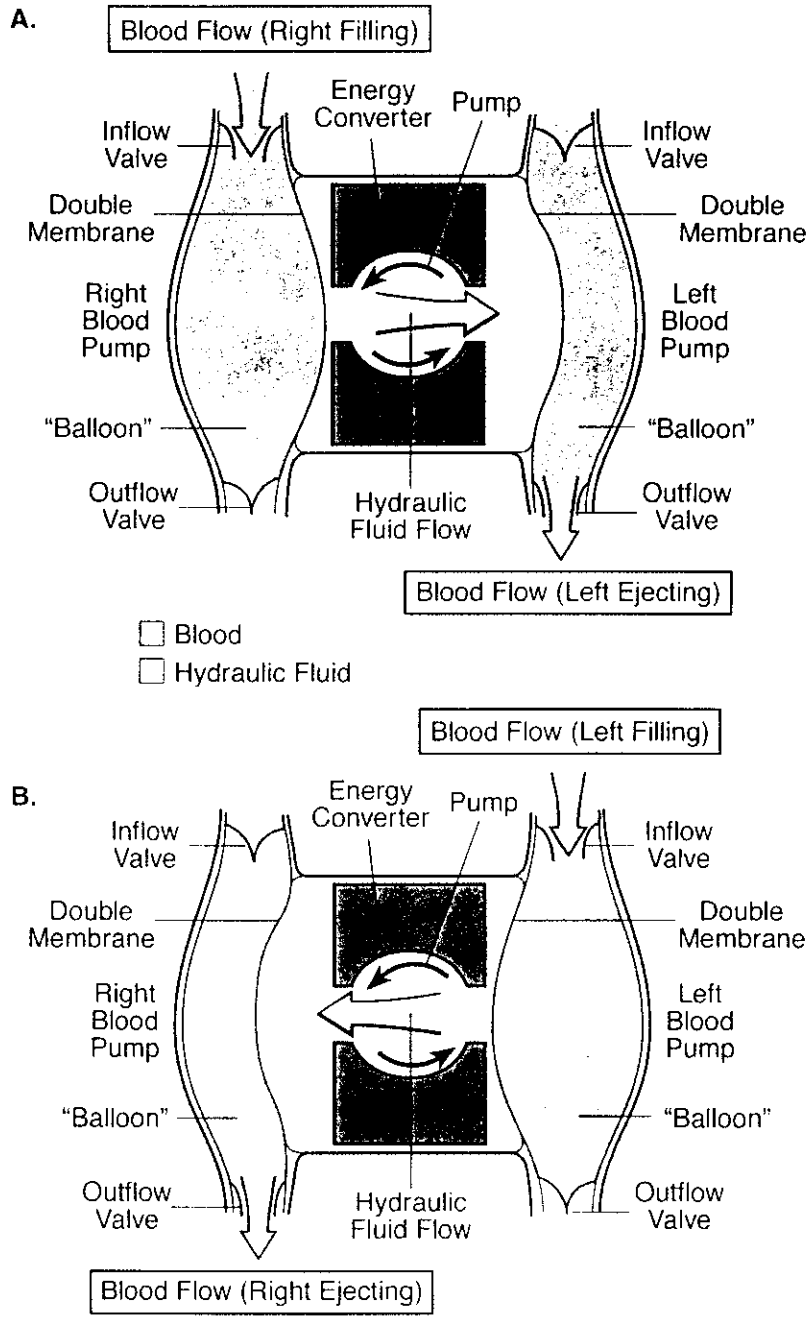

Figure 3.4 Concept of AbioCor Operation A) Left Systole/ Right Diastole B) Right Systole/Left Diastole

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Description

Energy Converter

The Energy Converter converts electrical energy into the pumping action. The key components are:

- A unidirectional hydraulic pump, with a motor that spins at 3,000 to 10,000 rpm to pressurize the hydraulic fluid. The motor speed controls the pressure of the hydraulic fluid.
- A bi-directional switching flow control valve, which can direct the flow of hydraulic fluid toward either side of the Energy Converter.
- Two pressure transducers, which measure the hydraulic fluid pressure on each side of the Energy Converter. These pressures are known as the Left Hydraulic Pressure (LHP) and Right Hydraulic Pressure (RHP).

These components are mounted in a metal artificial septum, which is filled with a silicone-based hydraulic fluid. Both sides of the casing are sealed by a flexible membrane.

The Energy Converter also contains the occluder valve, which is part of the left/right balance system described later in this section.

Left and Right Blood Pumps

The Left and Right Blood Pumps replace the patient's natural left and right ventricles and simulate their pumping action. Each pump contains a one-way inflow valve, a pumping chamber lined with a seamless Angioflex™ membrane (the "balloon"), and a one-way outflow valve. The inner face of each blood pump is flexible.

The Left Blood Pump also contains the Balance Chamber, which is part of the left/right balance system described later in this section.

When the Thoracic Unit is assembled, the Angioflex™ membranes in the blood pumps are in contact with the flexible membranes that seal the sides of the Energy Converter. This creates a flexible double membrane that allows hydraulic pressure from the Energy Converter to act on the blood pumps but prevents any mixing of blood and hydraulic fluid.

AngioFlex™

AngioFlex™ is a polyether-based polyurethane plastic used in the AbioCor Implantable Replacement Heart. A proven dependable and durable substance, Angioflex is used for the blood contacting surfaces of the AbioCor. It has been shown to be capable of flexing hundreds of millions of times without breaking.

Cuff and graft connections

The Thoracic Unit is implanted in the cavity created when the ventricles are removed. It connects to the patient's circulatory system using two cuffs and two grafts, as shown in Figure 3.5. These connections are located in approximately the same positions as those of a natural heart. During implantation, the cuffs are attached to the atrial tissue left behind after the ventricles are removed, and are joined to the Thoracic Unit inflow ports by quick-connect fittings. The grafts are attached to the aorta and pulmonary artery and are connected to the Thoracic Unit outflow ports.

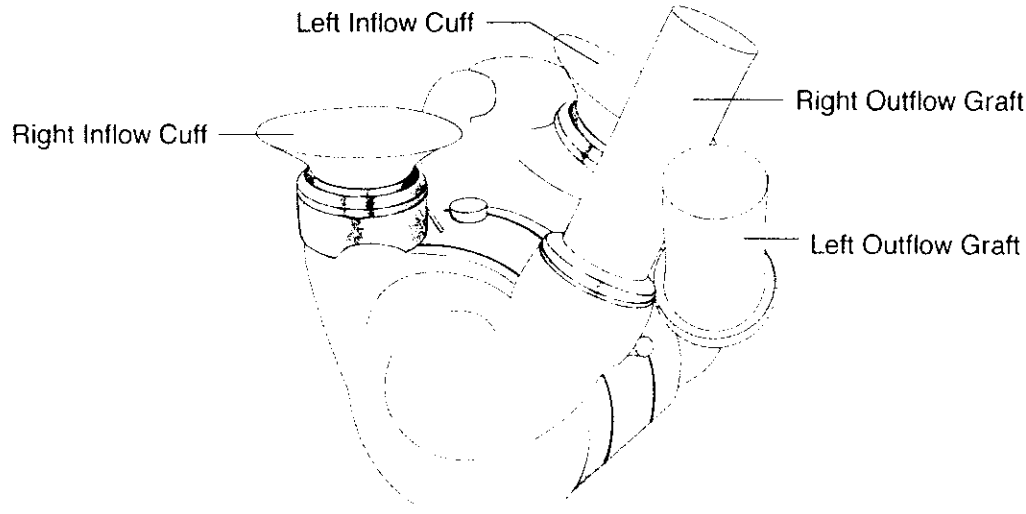

Figure 3.5 Cuff and Graft Connections

Operation

The Thoracic Unit simulates the pumping cycle of a natural heart by alternately ejecting blood from the left and right sides (refer back to Figure 3.4)

The pumping cycle consists of the following steps:

1) The hydraulic pump in the Energy Converter pressurizes the hydraulic fluid.

2) The bi-directional flow control valve directs the pressurized hydraulic fluid away from the left blood pump and toward the right blood pump.

   The hydraulic fluid presses on the membrane between the right blood pump and the Energy Converter, squeezing the "balloon" in the right blood chamber and ejecting blood from it (right systole).

The speed of the hydraulic pump motor during this phase, known as the Right Motor Speed (RMS), controls the hydraulic fluid pressure and the force with which the blood is ejected. Higher motor speeds tend to give higher pressure. The RMS is controlled automatically by the AbioCor System.

At the same time, the fluid being pumped away from the left blood pump causes suction on the dual membrane between the left blood pump and the Energy Converter. This suction pulls blood into the left blood chamber, actively filling it (left diastole).

The one-way valves in the blood chambers ensure that the blood flows in the correct direction.

3) Next, the bi-directional flow control valve switches to direct the pressurized hydraulic fluid in the other direction, from right to left.

   The speed of the hydraulic pump motor during this phase (Left Motor Speed or LMS) controls the hydraulic fluid pressure and the force with which the blood is ejected. The LMS is controlled automatically by the AbioCor System.

   This ejects blood from the left blood chamber (left systole) while drawing blood into and filling the right blood chamber (right diastole).

4) The cycle repeats indefinitely.

   The frequency at which the bi-directional control valve switches (from right systole to left systole and back) is known as the Thoracic Unit's Beat Rate. The Beat Rate is set manually on the AbioCor Console.

Implications of the Thoracic Unit Design

The design and operation of the Thoracic Unit have several implications that are critical to understanding how the AbioCor System works.

- There is a close relationship between the movement of hydraulic fluid and displacement of blood. The amount of blood ejected from a blood pump is related to the amount of hydraulic fluid pumped to that side of the heart, and the amount of blood that fills a blood pump is related to the amount of hydraulic fluid pumped out of it.

- The AbioCor always draws blood into one blood pump while ejecting it from the opposite blood pump, because the hydraulic fluid that is pressurizing one chamber is being withdrawn from the opposite side. Thus, left systole always occurs simultaneously with right diastole and vice versa.

- The Thoracic Unit is an *actively* filled device, because it actively pulls blood into the left and right pump chambers rather than passively allowing them to fill. Clinically, this means that the AbioCor System is sensitive to low atrial pressures, which can cause inflow limiting or low blood flow, which is discussed in Section 6.

The natural imbalance between the flow through the left and right sides of the heart complicates this picture. The AbioCor Left/Right Flow Balance system, described below, allows users to manage the natural imbalance between flow in the left and right circulation.

Bronchial Shunt Flow and Left-Right Balance

The left side of the heart pumps more blood than the right side. Part of this difference results from bronchial shunt flow, which supplies oxygenated blood to the pulmonary tissues. In the bronchial shunt flow, some blood flows from the left ventricle to the pulmonary system via the bronchial artery, and back to the left atrium via the pulmonary veins. This flow is different from normal systemic circulation, which flows from the left ventricle and returns to the right atria. Other blood flows and the physical characteristics of the Thoracic Unit may also contribute to the imbalance between left and right flows.

Left/Right Flow Balance System

In a normal person, the right side of the heart pumps less blood than the left side of the heart because of bronchial shunt flow and other factors (see sidebar). To duplicate this difference, the AbioCor System produces lower flow from the right blood pump than the left blood pump. If the balance between the left and right flows is incorrect, the Left Atrial Pressure (LAP) will be too high (too much right side flow) or too low (not enough right side flow). The Left/Right Flow Balance System is used to keep the LAP within an appropriate range (10-15 mm Hg) by controlling the blood flow through the right blood pump.

During right systole, hydraulic fluid is pumped from the left hydraulic chamber towards the right blood pump. Simultaneously, hydraulic fluid is allowed to fill the balance chamber.

During left systole, hydraulic fluid is pumped from the Balance Chamber through the occluder valve and from the right hydraulic side to the left hydraulic side. When the left blood pump reaches full stroke, "extra" hydraulic fluid remains on the right side. This extra hydraulic fluid displaces volume that would otherwise be filled with blood.

The more extra hydraulic fluid remaining on the right side, the less the right side is allowed to fill with blood. Therefore, the right blood pump pumps less blood than the left blood pump.

The occluder valve controls the amount of hydraulic fluid diverted into and out of the Balance Chamber and therefore the left/right flow balance. Opening the occluder valve diverts more hydraulic fluid into the Balance Chamber and decreases the right side stroke volume and LAP. The left/right flow balance is set by the Balance Control, which ranges from 0 (occluder valve fully open, low LAP) to 400 (occluder valve fully closed, high LAP). The balance is set manually on the AbioCor Console.

Controls

The Thoracic Unit has four key settings, listed in Table 3.3, which affect cardiac output and blood pressure. Section 6 discusses how, when, and why to change these settings.

Table 3.3 Thoracic Unit Controls

Control	Range	Operation	Thoracic Unit Function	Patient	Notes
Beat Rate	80-150 bpm	Manual	Bi-directional control valve cycling frequency	Heart beat rate	Increasing the beat rate: ↑ Cardiac Output (CO) ↓ Right atrial pressure (RAP)
Balance	0-400	Manual	Occluder valve setting	Left atrial pressure (LAP)	Increasing the Balance Control setting tends to increase LAP.
Left Motor Speed	3,000-10,000 rpm	Automatic	Hydraulic pump speed during left systole	Force of blood ejection during left systole	Seldom needs to be changed
Right Motor Speed	3,000-10,000 rpm	Automatic	Hydraulic pump speed during right systole	Force of blood ejection during right systole	Seldom needs to be changed

Implanted Controller

Overview

The Implanted Controller (shown in Figure 3.6) is the brain of the implanted parts of the AbioCor System. It performs several critical functions:

- monitoring of the Thoracic Unit and the other implanted components
- control of the Thoracic Unit
- communication with the external components and alarms (the AbioCor Console or Patient-Carried Electronics)

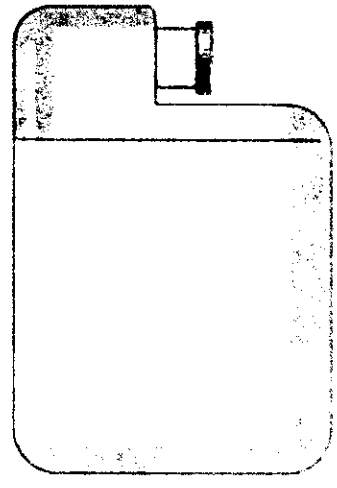

Figure 3.6 AbioCor Implanted Controller

The Implanted Controller contains the control electronics in a hermetically sealed titanium case. It is implanted abdominally, outside the peritoneum, on the patient's left side between the subcostal and iliac regions. It may be uncomfortable or painful when the patient is in certain positions, such as bending over to tie shoes.

Monitoring

The Implanted controller constantly monitors dozens of variables related to the operation of the AbioCor System's implanted components. These include the left and right hydraulic pressures and motor speeds, the temperatures of the implanted components. and voltages, currents and power levels in different system components.

If a critical variable goes outside its normal range, the Implanted Controller sends an alarm signal to the external components. See Alarms and Communications below for a more detailed description of alarm signaling, and Section 9 for more information on alarm messages.

Control

The Implanted controller drives the Thoracic Unit automatically using a variety of software algorithms and procedures. Table 3.3 above shows the controls that drive the Thoracic Unit.

The Implanted controller:

- Switches the bi-directional flow control valve back and forth according to the beat rate setting.
- Opens or closes the occluder valve according to the Balance setting.
- Sets the hydraulic pump motor speed for the left and right strokes. This is ordinarily done automatically using an internal software procedure known as the "Full Stroke Control (FSC) Algorithm." (see sidebar) However, the left and right motor speeds can be set manually from the AbioCor Console. There are also de-airing modes that control the motor speed independently of the left and right stroke, which are used only during implantation and not discussed further in this manual.

Automatic Left and Right Motor Speed Control

The Full Stroke Control (FSC) algorithm automatically sets left and right motor speed each time the Thoracic Unit beats, using the left and right hydraulic pressures measured throughout the stroke to ensure that each chamber pumps a full stroke.

Section 6 discusses how hydraulic pressure measurements are used.

Communications and Alarms

The Implanted controller uses two channels for communicating with the external components of the AbioCor System: the TET channel and the RF channel.

- TET Channel

  The TET Channel sends an alarm signal from the Implanted controller to the AbioCor Console or to the PCE whenever an alarm occurs. The signal indicates that an alarm condition is present, but gives no other information. The RF channel must be used to determine the nature of the alarm and correct it.

  The advantage of the TET channel is that it is very reliable: the TET does not move out of position easily and the TET channel is very resistant to electrical interference.

- RF Channel

  The RF Channel uses transcutaneous radio signals—radio-frequency (RF) waves—for communication between the Implanted controller and the external RF Communications Module. The advantage of the RF Channel is that it communicates detailed and complete information and commands, as shown in Table 3.4.

  However, RF communications are less reliable than those sent through the TET Channel:

  — RF communications will be disrupted if the RF Communications Module moves out of position.

  — The RF Channel is less resistant to electrical interference.

  — Patient movements, especially during sleep, commonly move the RF Module out of position.

The operator can choose the channel on which the system operates. It is recommended during hospital stays that the RF channel be active. For patients who are discharged to an intermediate care facility or to home, it is recommended that the TET channel mode be active. If an alarm occurs when in TET channel mode, the RF communications link automatically activates to allow the user to read the alarm condition on the Console.

See Section 9 for more information on warnings and alarms, and Sections 4 and 5 for information on using the AbioCor Console to monitor and control the implantable components.

Table 3.4 RF Channel Communications

Data	Sent from:	Sent to:
Warnings and alarms	Implanted controller	AbioCor Console or PCE
Monitoring data	Implanted controller	AbioCor Console or PCE
Commands and Settings	AbioCor Console	Implanted controller

Implanted TET

The Implanted TET, shown in Figure 3.7 receives electrical energy in the form of radio waves from the External TET and converts it to the DC power used by the rest of the AbioCor System.

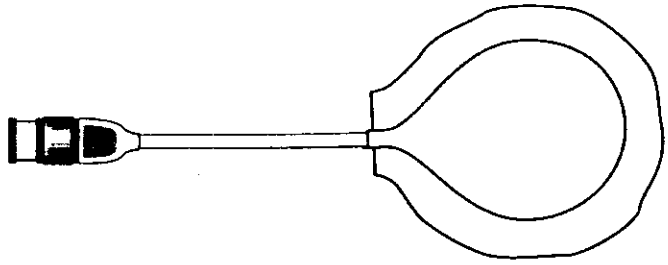

Figure 3.7 AbioCor Implanted TET

The Implanted TET is positioned in a subcutaneous pocket, usually in a subclavicular location. The details of the location depend on the patient's size and other anatomical considerations.

The Implanted TET is the primary power source for the AbioCor System's implanted components. Because the radio waves used can pass through a small thickness of human tissue, no percutaneous connections are needed. In addition, the Implanted TET can transmit an alarm signal when the TET Alarm Channel is in use.

As discussed in the warnings and precautions section, metal objects near either the Implantable or External TET can disrupt power transmission between them. When this occurs, some of the power is converted to heat and can cause burns.

If the External TET is misaligned or the implantable components are running at high power, the Implanted TET can heat up, causing patient discomfort or thermal injury. Management of the Implanted TET is discussed in Section 6.

Implanted Battery

The Implanted Battery, shown in Figure 3.8, contains enough electrical energy to drive the AbioCor System for approximately 30 minutes with no external power supply. This allows the patient to function without a Console or PCE for short periods. The actual length of operation on the Implanted Battery depends on the age and charge of the battery and on the blood flow rate provided by the AbioCor System.

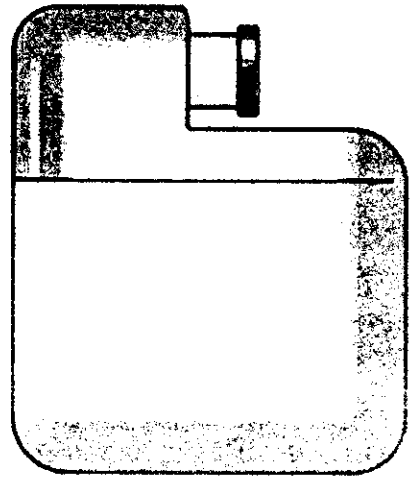

Figure 3.8 AbioCor Implanted Battery

The Implanted Battery is located abdominally, outside the peritoneum, on the patient's right side between the subcostal and iliac region. In this location, the battery can be replaced by a minor surgical procedure. Because the AbioCor System can get power externally, through the TET, the battery can be replaced without interrupting the operation of the AbioCor System.

The Implanted Battery recharges automatically whenever the implantable components are drawing power from the TET. The battery should be kept at full charge whenever possible because it takes 4 or more hours to recharge, as shown in Table 3.5.

Table 3.5 Implanted Battery Recharge Times at Different Charge Levels

Battery Charge Level	Time to fully Recharge (hours)
Seriously Low (Yellow alarm)	4
Life-threateningly Low (Red alarm)	15

The Implanted Battery may cause discomfort or pain in some postures, such as bending over to tie shoes. In the unlikely event that the implantable components are run at high power from the Implanted Battery, it can heat up, causing patient discomfort or thermal injury.

Implanted interconnecting Cable

The Implanted interconnecting Cable, shown in Figure 3.9, provides electrical connections between the other internal components of the AbioCor System, and contains the antenna for communicating with the Console and RF Communications Module.

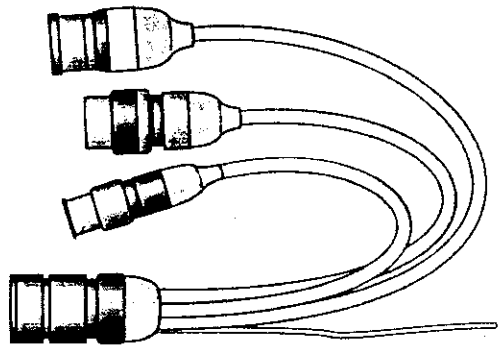

Figure 3.9 AbioCor Implanted Interconnecting Cable

The remaining AbioCor System components in this section are the *external* components required for operation of the AbioCor System. Without the external components, the internal components cannot get power or signal alarm conditions.

Note: A backup external system (Console or PCE) should be available at all times. [The Console is discussed below. The PCE is discussed in Appendix A and in more detail in a separate Patient-Carried Electronics (PCE) manual.]

AbioCor Console

The AbioCor Console, shown in Figure 3.10, is the central external component of the AbioCor System. It provides power and data communications to the internal components, and is the interface for other patient monitoring equipment, data logging, networking, remote monitoring by ABIOMED, and other external functions. The Console transmits power via the TET, and communicates via the RF Communications Module.

Console operation is described in detail in the next sections.

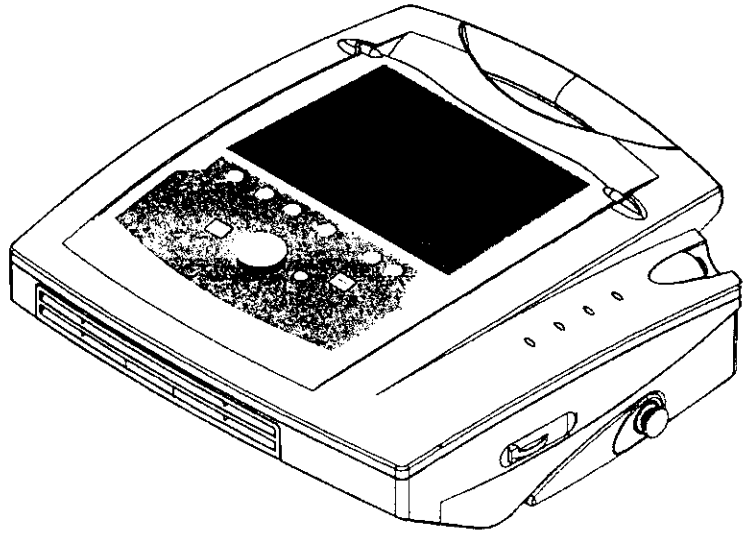

Figure 3.10 AbioCor Console

External TET

The External Transcutaneous Energy Transfer coil (TET), shown in Figure 3.11, provides power in the form of radio waves to the Implanted TET, which then powers the implanted components of the AbioCor System. In addition, the External TET detects alarm conditions when the TET Alarm Channel is in use. The External TET contains a coil antenna tuned to send radio energy to the Implanted TET. The coil is connected to the Console by an 11-foot or a 5-foot cable.

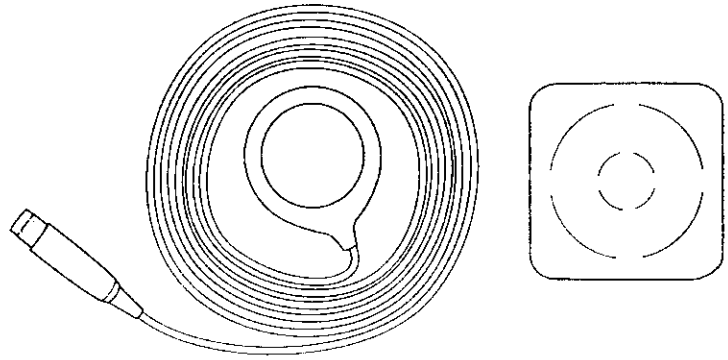

Figure 3.11 AbioCor External TET and DuoDerm® Patch

As discussed in the precautions section, metal objects near either TET will disrupt the power transmission so that some of the power becomes heat, which can damage the electronics and/or injure the patient.

The External TET is attached to the patient's skin using a custom-designed DuoDerm® adhesive patch (see Figure 3.11), and should be positioned directly over the Implanted TET. The proper positioning and use of the DuoDerm patch is shown in the Patient Manual.

RF (Radio Frequency) Communication Module

The RF Communication Module (see Figure 3.12) uses radio communications (similar to a cell phone or a wireless network) to send data between the Implanted controller and the Console or the Hand Held monitor.

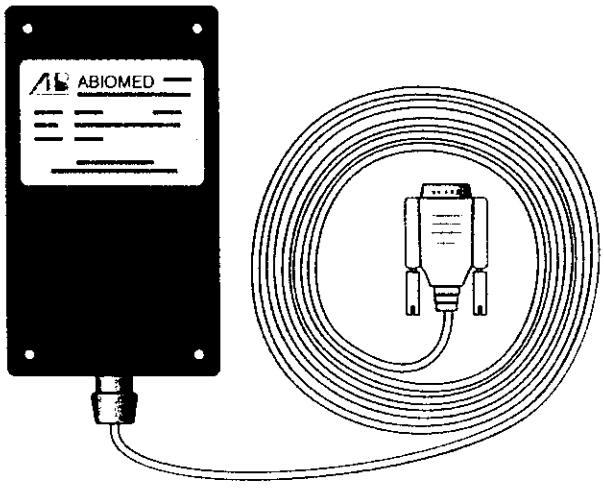

Figure 3.12 AbioCor RF Communication Module

For reliable communications, the RF Communication Module should be kept directly on the patient's abdomen in the area above the Implanted Controller. The RF Communication Module is connected to the Console by a communications cable. Misplacement of the RF Communication Module is a common cause of AbioCor Console alarms.

It is theoretically possible for any device that transmits radio signals to interfere with the communications between the RF Communication Module and the Implanted controller. In practice, RF interference problems are rare. Such problems, if they occurred, would probably affect only data communications and would not affect the operation of the internal components. Devices that could theoretically cause interference include cell and wireless phones, two-way radios, vacuum cleaners or other appliances with large electric motors, and wireless computer networks.

4 Using the AbioCor Console

Contents

Console Connections and Set Up

Electrical connections to the Console are made through the back panel. The connections are shown in Figure 4.1 and are listed and briefly described in Table 4.1. Each connector is unique and keyed to ensure that connections are made correctly.

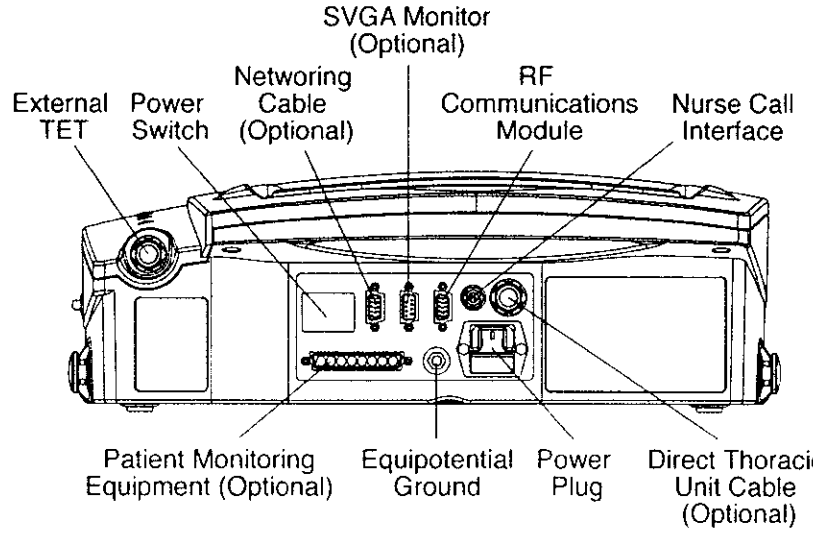

Figure 4.1 AbioCor Rear Panel and Connections

Table 4.1 AbioCor Console Connections

Connection	Description
Required Connections: essential to proper function of the AbioCor System	
External RF Communication	Connects to the RF Communication Module (refer to Section 3)
External TET connector	Connects to the External TET (refer to Section 3)
AC power connector	Provides AC power to the AbioCor System

Table 4.1 AbioCor Console Connections (continued)

Connection	Description
Optional Connections: may be used in specific circumstances	
Patient Monitoring Equipment	Accepts analog inputs from patient monitoring equipment (see Appendices for interfacing and calibration information) Intended to accept Aortic Pressure (AoP), Left Atrial Pressure (LAP), and Right Atrial Pressure (RAP) for display as waveforms and numeric values in Clinical Mode Used only for data collection and should not be used for patient monitoring
Equipotential ground	Used to ground the AbioCor Console according to hospital procedures
SVGA Monitor connector	Connects to an SVGA monitor to provide a more visible screen
Network Connector	Connects to the hospital network for data downloading
Thoracic Connector	Connects the AbioCor Console directly to the Implanted controller Used only during implantation.
Nurse Call Interface	Connects the AbioCor Console to the hospital nurse call system

Plug the Console in to AC Wall Power.

If the console will be used for remote monitoring by ABIOMED, contact ABIOMED and/or the hospital's information systems department for assistance in setting up the remote monitoring.

Do not connect the External TET until you are about to use it on a patient. This helps ensure that the External TET is not damaged by close proximity to metal objects. Before connecting the TET, ensure that it is positioned away from metal objects and other External TET coils, and that it is not resting on a metal surface.

Turning the Console ON

The Console power switch is on the back panel. It is a white rectangular switch, protected by a clear plastic cover, which keeps the Console from being accidentally turned off.

To turn on the Console, flip the plastic cover up so that the power switch is exposed. Press the power switch once. The Console makes some clicking noises as it goes through a self-test routine, and then beeps to tell you the system is working correctly. The display on the front of the Console will light up and show either the Home Screen or the Clinical Screen, depending on which mode it was in before it was turned off.

Console features

The key mechanical features of the AbioCor Console are shown in Figure 4.2 and described in Table 4.2.

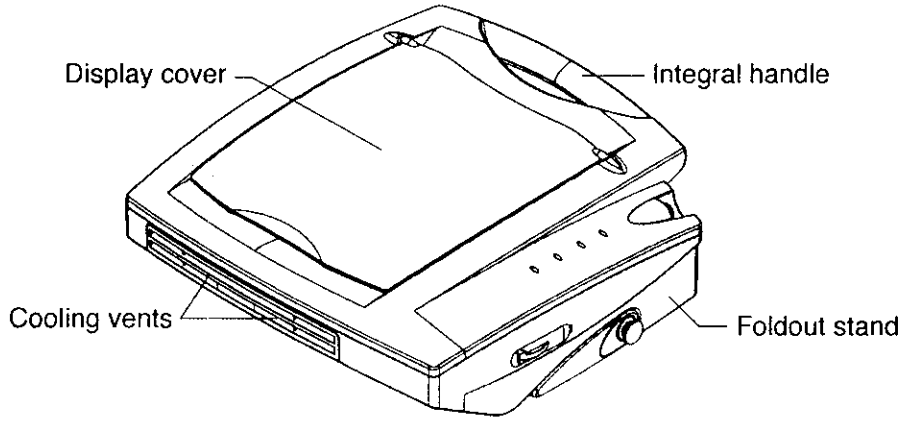

Figure 4.2 Console Features and Components

Table 4.2 Mechanical Features of the AbioCor Console

Feature	Description
Carrying handle	Used for transporting the Console
Display cover	Protects the LCD display during transit Can be raised or removed
Foldout stand	Folds in or out depending on whether the Console is being used in either a horizontal or an angled position
Cooling vents	Provide cooling air for the Console Vents must be kept clear (e.g., from sheets or bedding) to ensure proper Console operation

Console controls and indicators

The AbioCor Console includes a variety of controls and indicators used to monitor and control the operation of the AbioCor System. Figure 4.3 and Table 4.3 identify and describe the Console controls and indicators.

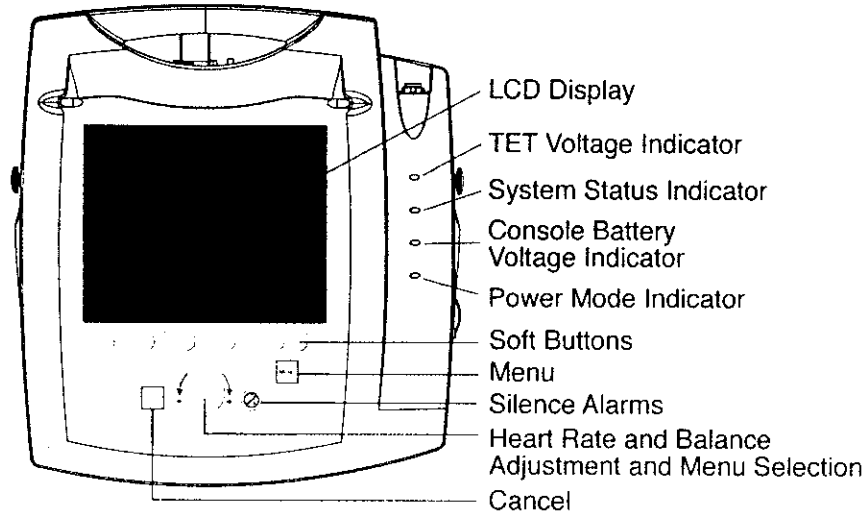

Figure 4.3 AbioCor Console Controls and Indicators

Table 4.3 Console Displays, Controls, and Indicators

Feature	Use
Display	
LCD Display	Displays a variety of information
Console Controls and Buttons	
Menu Button	Press to show the menu
Selector Knob	Rotate the knob to highlight different menu items or operating parameters Press the knob to select the highlighted menu item or parameter
Cancel Button	Removes all menus and dialog boxes from the display
Silence Alarm Button	Press to temporarily silence all active alarms
Soft Buttons	The function of these buttons is controlled by software and changes as needed depending on the screen, menu, or dialog shown on the LCD display
Indicator Lights	
TET Voltage	Color indicates TET status Green Normal (28-32 Volts) Orange Poorly coupled Red Disconnected
System Status	Color indicates TET status Green Normal Orange Needs attention Red Possible critical condition
Console Battery	Color indicates Console Battery voltage Green Normal Orange Low
Power Mode	Color indicates the power source for the system Green AC Wall power Red Console battery power

Console operating modes

Clinicians, patients, and caregivers use the AbioCor Console to view and control the AbioCor System's operating parameters. Clinicians also use it to monitor and assess hemodynamic information. The AbioCor Console supports these uses with two operating modes:

- Clinical Mode
- Home Mode

Clinical Mode

Clinical Mode is intended for use by clinicians familiar with the care of cardiac patients and trained in operating the AbioCor System. It provides complete information on the AbioCor System status, and allows manual control of AbioCor operation. It also displays hemodynamic information and waveforms. In addition, Clinical Mode allows access to Implant Mode, which is used only during surgery to implant the AbioCor System, and is not discussed in this manual. Clinical Mode is password protected.

Figure 4.4 shows a sample Clinical Mode screen, and this manual describes the Clinical Mode in Section 5.

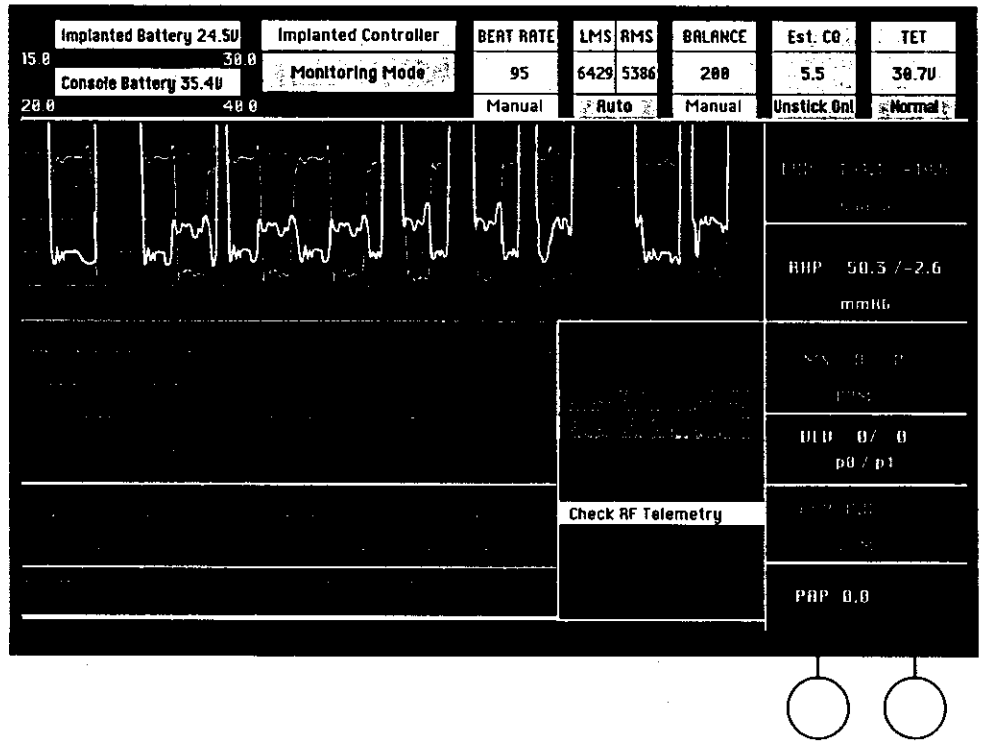

Figure 4.4 Sample Clinical Mode Screen

Home Mode

The Home Mode is intended primarily for use by patients, caregivers, and clinicians, in the home environment. It provides limited patient-friendly and easy to use monitoring and control of the AbioCor System. Figure 4.5 shows a sample Home Mode screen.

Clinicians may want to use Home Mode in the hospital after the patient has recovered from implantation surgery and is in a stable condition. This familiarizes patients with using the Home Mode and allows easy access to frequently needed information and controls.

This manual provides a summary description of the Home Mode in Appendix B. A complete description is located in the separate Patient Manual.

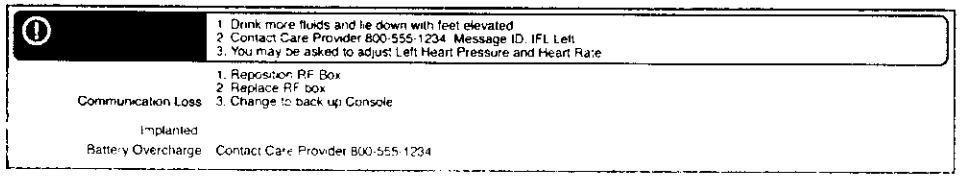

Figure 4.5 Sample Home Mode Screen

Changing from Clinical Mode to Home Mode

Follow these instructions to change from Clinical Mode (the "Clinical Screen") to Home Mode (the "Home Screen"):

How to Change from Clinical Mode to Home Mode

Your Action	AbioCor Console Response
1. Press the Menu button	Main Menu appears
2. Turn the Menu Selector Knob to select the View menu	View option is highlighted
3. Press the Menu Selector Knob	View menu appears
4. Turn the Menu Selector Knob to select the Enter Home Screen option	Enter Home Screen option is highlighted
5. Press the Menu Selector Knob	Home Screen appears

Changing from Home Mode to Clinical Mode

Follow these instructions to change from Home Mode to Clinical Mode:

How to Change from Home Mode to Clinical Mode	
Your Action	**AbioCor Console Response**
1. Press the Menu button	Menu appears
2. Turn the Menu Selector knob to select "Enter Clinical Screens" on the Menu	"Enter Clinical Screens" option is highlighted
3. Press the Menu Selector Knob	Soft buttons are relabeled with letters as shown in Table 4.4
4. Press the soft buttons in sequence to spell "H-E-A-R-T" (2,2,1,6,6)	Clinical Screen appears

Table 4.4 illustrates the soft button functions for Password Entry.

Table 4.4 Soft Button Functions for Password Entry

Button Number	1	2	3	4	5	6
Home Screen Icon	RF Panel	Power Panel	Heart Rate	Balance	Test PCE Alarm	Deactivate Console
Password Entry Icon					Not used	

5 Using the Console: Clinical Mode

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Overview

This section provides information on the basics and details of using the Clinical Mode. In Clinical Mode, the Main Screen shows a wealth of information on the status of the AbioCor system and the patient's hemodynamics. Menus and popup dialogs allow clinicians using the system to view and change AbioCor operating parameters and settings.

This section discusses:

- the Main Screen
- the Parameter Popup
- How to Navigate Menus and Popups
- Descriptions of all Menus and Popups

Main Screen

The Clinical Mode Main Screen is divided into several areas, as shown in Figure 5.1 and described in Table 5.1.

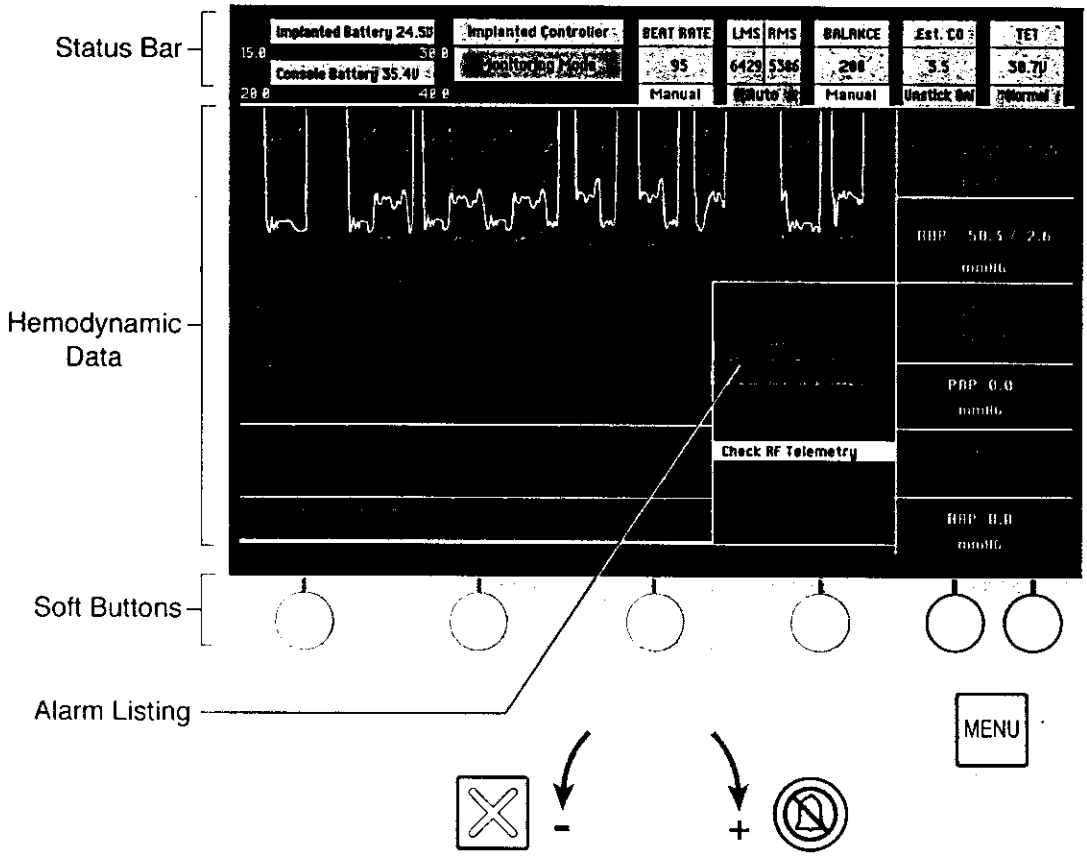

Figure 5.1 AbioCor Console Clinical Mode Main Screen and Keypad

Table 5.1 Clinical Mode Main Screen

Feature	Description
Alarm Listing	Lists the highest-priority active alarms
Hemodynamic Data	Displays hemodynamic data numerically and as waveforms
Status Bar	Shows the status of critical AbioCor parameters
Soft Buttons	Used to control the Beat Rate, Balance, and Motor Speeds

The control buttons and the Selector Knob operate as described in "Console Controls and Indicators" in the previous section.

Alarm listing

The alarm listing area lists all active and resolved alarms. If an alarm occurs, this area shows the name of the alarm and a short message suggesting the nature of the problem. The alarm message is shown until the condition causing the alarm is resolved.

The alarms are color coded by severity. For more information on a specific alarm, refer to the AbioCor Alarm Guide or Section 9.

Hemodynamic monitoring displays

The AbioCor Console hemodynamic display area shows waveforms and numeric values representing hydraulic pressures from the AbioCor System. It can also show blood pressures from patient monitoring equipment. Figure 5.2 shows the locations of the displays on the screen.

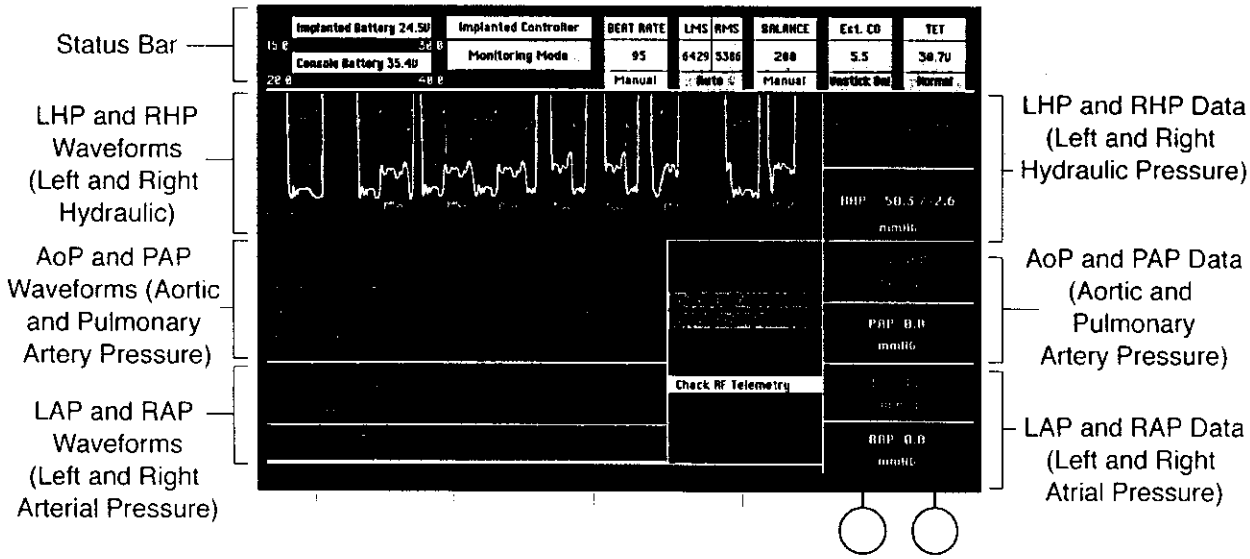

Figure 5.2 AbioCor Console Monitoring Screen: Waveform Area

The waveform displays are scaled automatically. Values and waveforms from the left side of the heart are shown in red. Those from the right side are shown in blue.

The numeric displays show the hydraulic, systolic, and diastolic pressures in mm Hg.

The pressure values shown on the AbioCor Console Monitoring Screen are listed in Table 5.2.

Table 5.2 Pressure Values

Pressure Measurement (mm Hg)	Notes
Left Hydraulic Pressure (LHP)	Measured by pressure transducers in the AbioCor Thoracic Unit
Right Hydraulic Pressure (RHP)	
Aortic Pressure (AoP)	Measured with patient monitoring equipment. Only displayed if the appropriate instrumentation is connected to the AbioCor
Pulmonary Artery Pressure (PAP)	
Left Atrial Pressure (LAP)	
Right Atrial Pressure (RAP)	

Waveforms and values from the AbioCor System are shown only if RF Communications are working.

To show waveforms and values from patient monitoring equipment, the equipment must be correctly connected, and the Console correctly calibrated for it, as discussed in Appendix H. Waveforms and values from patient monitoring equipment are intended only for data collection and are not to be used for patient management. If no equipment is connected, the values will be small and constant, and the waveform will be a flat line.

Status bar

The status bar area, shown in Figure 5.3, shows the values and settings of critical AbioCor System parameters. Key information for each parameter is summarized in the following text.

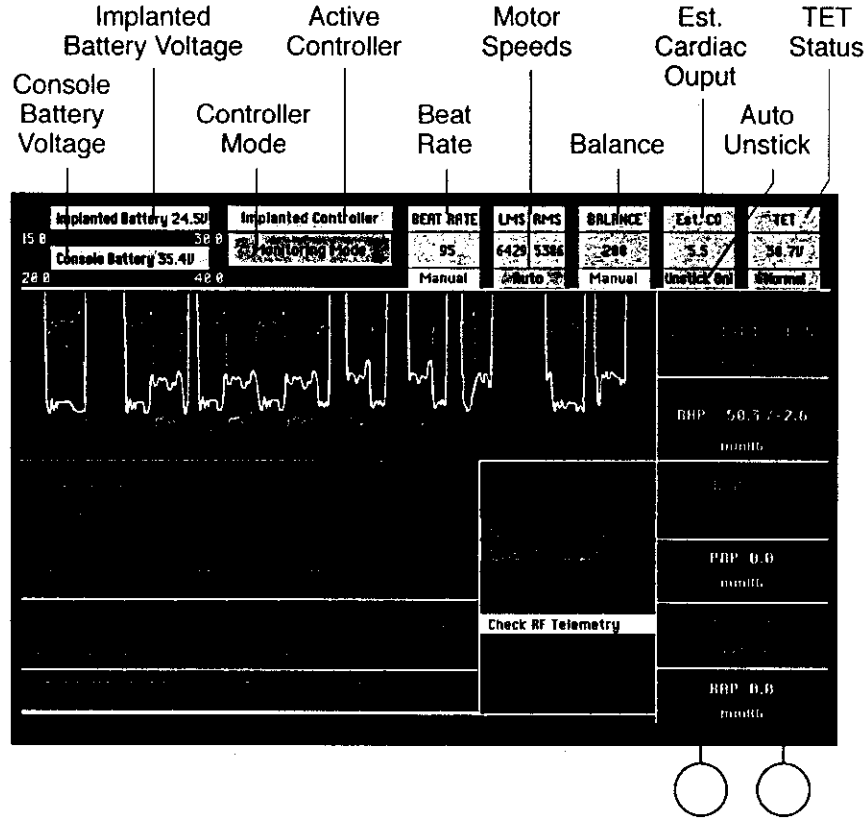

Figure 5.3 AbioCor Console Monitoring Screen Status Bar

Implanted Battery Voltage: Shows the Implanted Battery voltage numerically and as a bar graph, with color corresponding to the battery state.

Parameter Displayed	Possible Values	Background Colors
Implanted Battery Voltage (Volts) Combined numeric and bar graph display	19.0 to 25.0 V	Depends on battery state: Charged (> 21.5 V) Green Low (21.1 to 21.4 V) Yellow Critically Low (< 21.0 V) Red

Console Battery Voltage: Shows the Console battery voltage numerically and as a bar graph, with color corresponding to the battery state.

Parameter Displayed	Possible Values	Background Colors
Console Battery Voltage (Volts) Combined numeric and bar graph display	20.0 to 34.5 V	Depends on battery state: Charged (> 32.5 V) Green Low (31.6 to 32.4 V) Yellow Critically Low (< 31.5 V) Red

Active Controller: Displays the active controller.

Parameter Displayed	Possible Values	Background Colors
Active Controller	Implanted Controller	White

Controller Mode: Displays the Implanted controller operating mode.

Parameter Displayed	Possible Values	Background Colors
Controller Mode	Monitoring Mode	Green
	Implant Mode	Yellow

Parameter Displayed	Possible Values	Background Colors
Power Source	Console AC	Green
	Console Battery	Yellow Red (if the battery charge is low)
	Implanted Battery	Yellow Red (if the battery charge is low)

Beat Rate: Displays the current beat rate in beats per minute (bpm) and the Beat Rate Control Mode.

Parameter Displayed	Possible Values	Background Colors
Beat Rate	85 to 150 bpm	White
Beat Rate Control Mode		
	Manual	Yellow

Motor Speeds: Displays the current left and right motor speeds and the Motor Speed Control Mode.

Parameter Displayed	Possible Values	Background Colors
Left Motor Speed	3,000 to 10,000 rpm	White
Right Motor Speed	3,000 to 10,000 rpm	White
Motor Speed Control Mode	Automatic	Green
	Manual	Yellow

Balance: Displays the current balance setting and the Balance Control Mode.

Parameter Displayed	Possible Values	Background Colors
Balance	0 to 400	White
Balance Control Mode		
	Manual	Yellow

Estimated Cardiac Output: Displays the current estimated cardiac output.

Parameter Displayed	Possible Values	Background Colors
Estimated cardiac output (Est. CO)	Possible Range: 0-10 lpm Expected Range: 4-8 lpm	White Note: lpm = liters per minute

Auto Unstick: Indicates whether Auto Unstick is On or Off. Auto Unstick is ON by default. Please contact ABIOMED for assistance before changing the Auto Unstick setting.

Parameter Displayed	Possible Values	Background Colors
Auto Unstick	Unstick On	Green (Default)
	Unstick Off	Yellow

TET Status: Displays the TET voltage level and status.

Parameter Displayed	Expected Values	Background Colors
TET Voltage (Volts) Combined numeric and bar graph display	28.0 to 32.0 V	Depends on the voltage: High (> 45.0 V) Yellow Good (28.0 to 45.0 V) Green Low (24.6 to 28.0 V) Yellow Critically Low (< 24.6 V) Red Note: if the voltage is less than 26 V, the system runs from the implanted battery.
TET Coupling	Normal	Green
	Not coupled*	Yellow
	Not connected†	Red

*** Not coupled = Implantable and External TETs are not aligned.**

† Not connected = External TET is not connected to the Console.

Soft Buttons in the Main Screen

In the main screen, the four right-hand soft buttons allow control of the Beat Rate, Balance, Left Motor Speed, and Right Motor Speed, as shown in Figure 5.4. These parameters directly control the operation of the Thoracic Unit. The two left-hand soft buttons are not used.

The use of these controls are described in detail in Section 6. In summary, the steps required to change a Thoracic Unit setting are:

1. Show the Control Button Labels (Menu/Show Control buttons!)
2. Press the soft button for the desired control
3. Rotate the Selector Knob until the Control Button label shows the desired value
4. Press the Selector Knob to activate the new setting

The left and right motor speeds (LMS and RMS) are normally controlled automatically, and should not be changed. Manual operation is seldom used except during implant surgery, and should only be undertaken by advanced users or ABIOMED personnel.

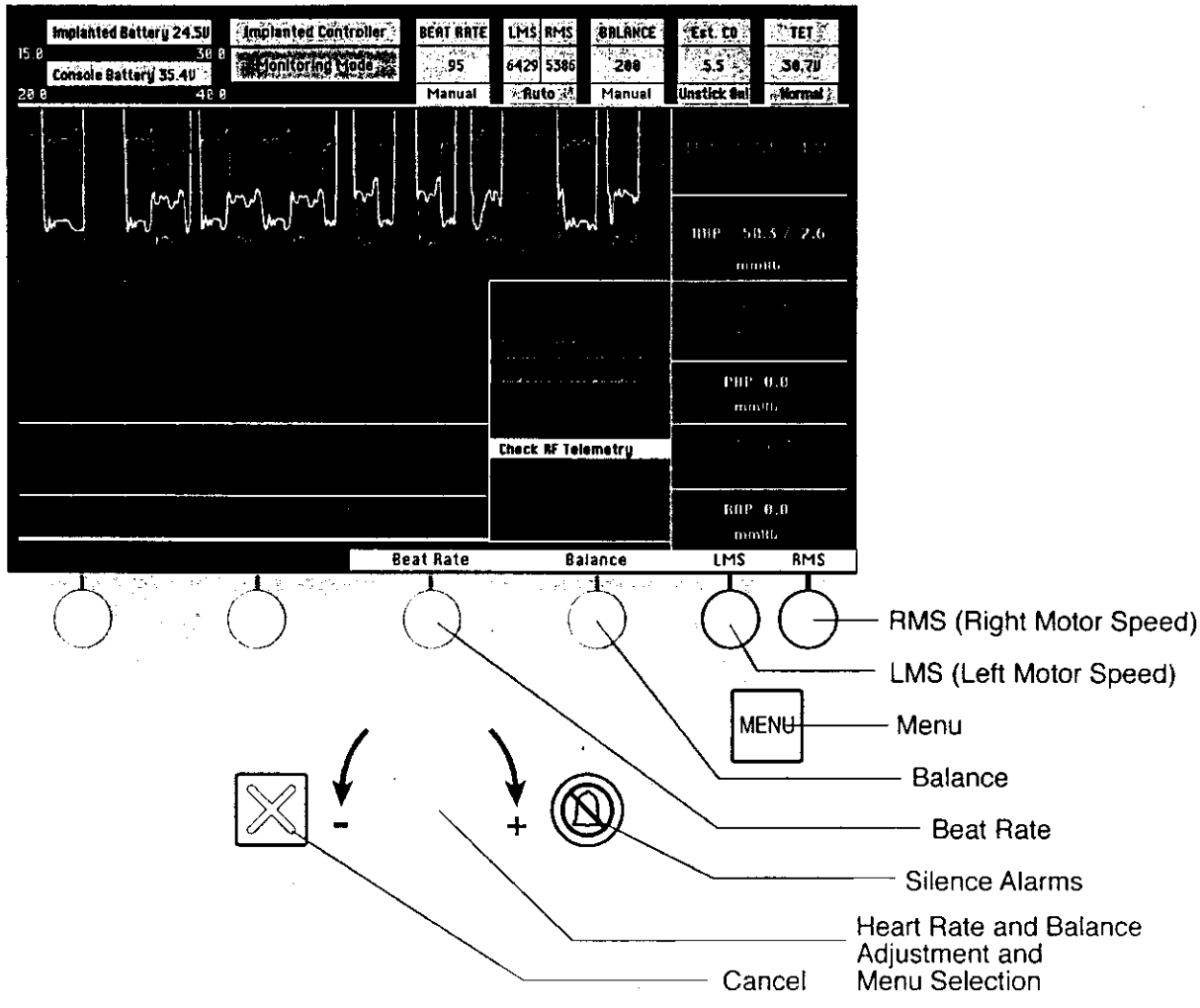

Figure 5.4 AbioCor Console Soft Buttons in the Main Screen

Parameter Popup Window

The Clinical Mode can display a Parameter Popup Window (see Figure 5.5) that displays important information on the power levels, temperature, and communications status of the AbioCor System. The popup screen is most often used to monitor the quality of RF communications while positioning the RF Communications Module. It is also used to get a more detailed look at the AbioCor System's power consumption and charge level than the Main Screen Status Bar provides.

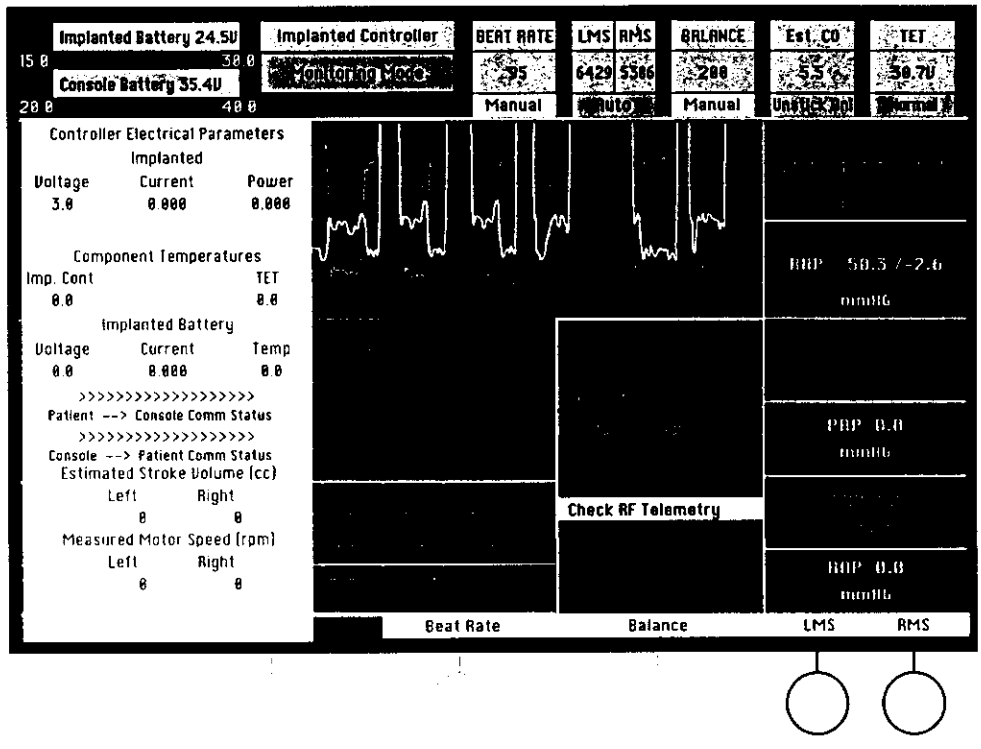

Figure 5.5 Clinical Mode Parameter Screen

Use the Main Menu to display the Parameter Popup Window, as follows:

1. Press the Menu button

   The main menu appears.

2. Rotate the Selector Knob until "Show Param Window!" is highlighted.

3. Press the Selector Knob.

   The Parameter Window appears, as shown in Figure 5.5.

Table 5.3 describes the information shown in the Parameter Window.

Table 5.3 Information Shown in the Parameter Window

Group	Title	Units	Expected Range	Description and Notes
Implanted Controller Electrical Parameters	Voltage	V	XX-XX	The voltage, current, and power being used by the implantable system.
	Current	A	XX-XX	
	Power	W	XX-XX	
Component Temperatures	Imp. Cont.	C	XX-XX	The temperature of the Implanted controller and the Implanted TET.
	TET	C	XX-XX	
Implanted Battery	Voltage	V	21.0 to 25.0	The voltage of the Implanted Battery. Higher voltages indicate more charge.
	Current	A	XX-XX	The current being drawn from the Implanted Battery. High current means that the battery is being drained quickly.
	Temp	C	XX-XX	The temperature of the Implanted Battery.
Patient --> Console Comm Status	See the description below			
Console --> Patient Comm Status				
Estimated Stroke Volume	Left	cc	30 to 60	The volume of blood ejected from the left or right blood chamber with each stroke.
	Right	cc	30 to 60	
Measured Motor Speed	Left	rpm	3,000 to 10,000	The hydraulic pump motor speed during left and right systole.
	Right	rpm	3,000 to 10,000	

Unit Abbreviations: V = Volts, A = Amps, W = Watts, C = degrees Celsius, cc = cubic centimeters, rpm = revolutions per minute

Implanted Component Temperatures

WARNING: If these are too high, they may cause patient discomfort or thermal injury. High implanted component temperatures can result from high power operation (fast beat rate), poor TET alignment, or an electronic problem.

Communication Status

The communication status displays show the quality of RF communications between the Console and the Implanted Controller during the last few seconds.

The displays can show the following symbols:

> Good RF communications

x RF interference or static (some data and commands may be lost)

0 No RF signal

These symbols move across the screen from left to right.

Clinicians can use these displays to check and adjust the position of the RF Communications Module by observing the display while moving the RF Communications Module. The Module is in a good position when the display consistently shows ">" (good RF communications) symbols.

Navigating in Menus and Popup Dialogs

The Clinical Mode menus and dialogs allow clinicians and ABIOMED engineers to view and set the parameters that control the operation of the Console and Implanted Controller. The menus and dialogs are accessed through the Main Menu, shown in Figure 5.6.

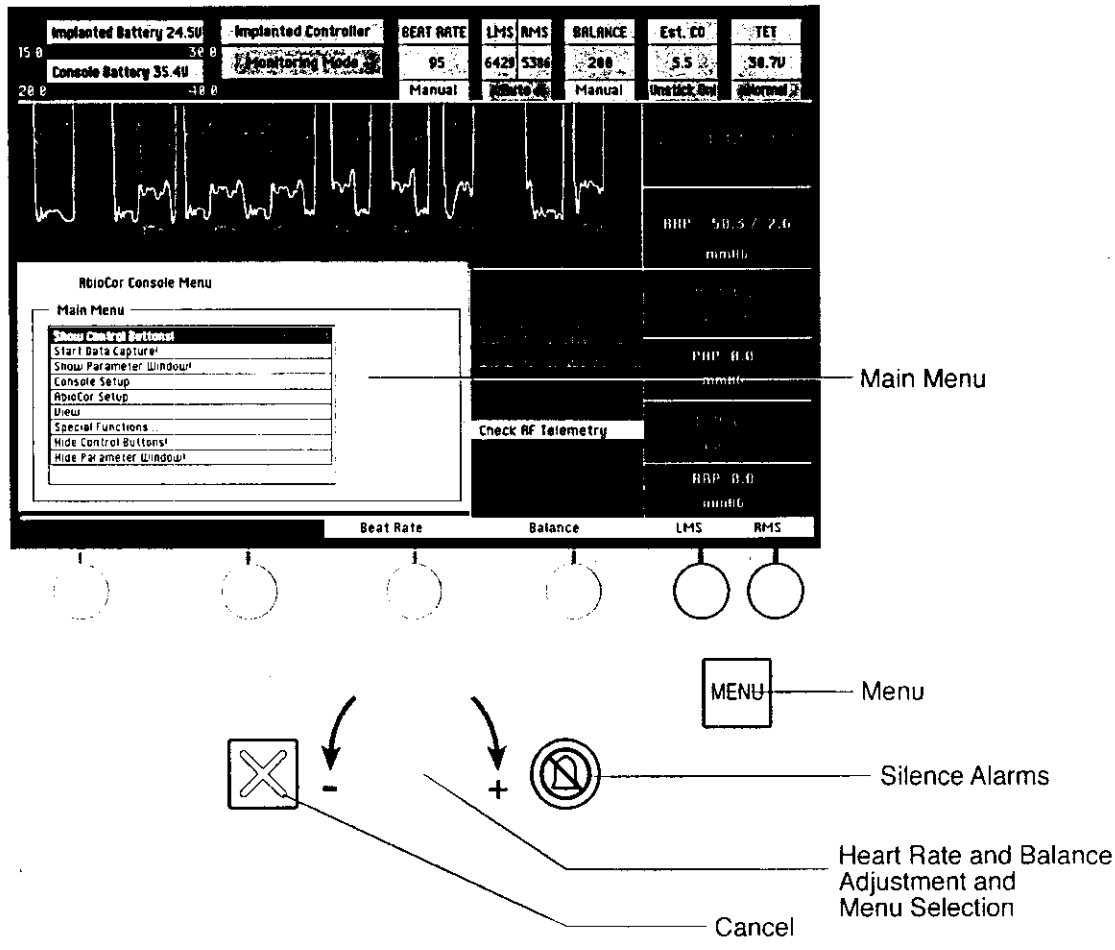

Figure 5.6 AbioCor Console Main Menu

Some of the menus and dialogs are intended for use only by advanced users or in consultation with ABIOMED, and some are intended only for use by ABIOMED engineers. These menus and dialogs are noted in this manual but not discussed further. The AbioCor Console does not restrict access to these menus except for the password required for access to the Clinical Mode in general. In addition, an Entry Confirmation box pops up when users attempt to access a menu section that allows changes that could possibly harm the patient. Clinicians who will use the Console should receive training regarding which menus and dialogs they should and should not use.

This section describes how to move between items in the menus and popup dialogs, and how to change values in popup dialogs. The next section gives more detailed information on the function of each menu item, and the corresponding popup dialogs when applicable.

Navigating Through the Menus

To use and navigate through the menus:

Your Action	AbioCor Console Response
1. Press the Menu button	The Main Menu appears All but one of the menu items have black text on a white background. The selected menu item is highlighted by showing white text on a blue background.
2. Turn the Menu Selector Knob to select the desired menu item. Rotating the knob clockwise moves the selection up, rotating it counterclockwise moves the selection down.	The highlighted menu item changes as the knob turns.
3. Press the Menu Selector Knob	The selected menu item activates. The AbioCor takes some action, shows a new menu or popup, etc.
4. Press the Cancel button to clear the current menu.	The Main Screen is displayed.

Some menu items end in special characters indicating their function:

Special character	Function indicated
!	Activating the menu item triggers some action
...	Activating the menu item displays a submenu

Popup Dialog Navigation

Navigation within AbioCor Popup Dialogs works much like Windows Dialog Boxes. Turning the Selector Knob acts like moving the mouse, pressing the Knob acts like a left-click.

Navigating Through Popup Dialogs

Popup dialogs allow users to set parameters related to particular AbioCor functions. There are a variety of popup dialogs, listed in Table 5.4. Figure 5.7 shows the Stroke Control Limits Setup popup dialog as a sample.

To use and navigate through a popup dialog:

Your Action	AbioCor Console Response
1. Use the menus to show the desired popup dialog.	The popup dialog appears, in the lower left corner of the display.
2. Use the Selector Knob to select, activate, and change dialog items as needed.	Turning the Selector Knob moves the light gray selection box.
3. Press the Cancel button at any point to clear the popup dialog without changing any values.	The Main Screen is displayed.

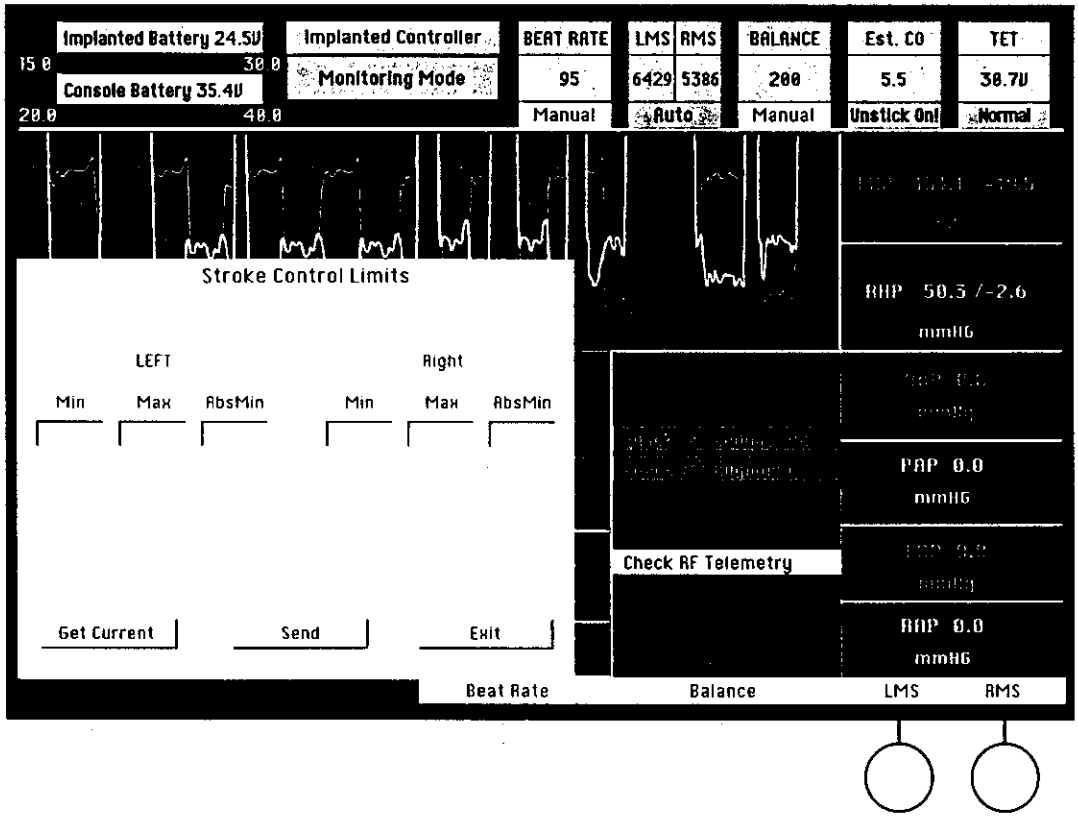

Figure 5.7 AbioCor Console Popup Dialog

Menu Item and Popup Descriptions

This section describes the use and purpose of all of the Console menus and popups. Table 5.4 lists all of the menu items according to the structure of the AbioCor menus and submenus.

Table 5.4 AbioCor Menu Structure

Menu Item	Intended Users
Show Control Buttons!	Clinicians
Start Data Capture!	Clinicians
Show Param Popup!	Clinicians
Console Setup...	
Patient ID	Clinicians
Date/Time	Clinicians
Input Phone Numbers	Clinicians
Input Beat Rate Range	Clinicians
Alarms...	Advanced
Pump Technical	Advanced
Physiologic / Control	Advanced
Power Controller	Advanced
Power Console	Advanced
RF Telemetry	Advanced
Implanted Controller Technical	Advanced
Console Technical	Advanced
Log Only Alarms	Advanced
Alarm Delay	Clinicians
Clear TET Fault Alarm.	ABIOMED
RF / TET Channel mode selection.	Clinicians
Enter Standby Mode!	Clinicians
Exit Standby Mode!	Clinicians
Setup FTP	Clinicians
Waveform Selection	ABIOMED
IC Battery Timer Delay Setup	ABIOMED
Console Calibration...	Clinicians
Calibrate All Physiologic Inputs	Clinicians
Establish Est. Phy. Inputs	ABIOMED
Abiocor Setup...	
Select Controller	Clinicians
Automatic Control Parameters...	Advanced
Stroke Control Parameters	ABIOMED
Balance Control Parameters	ABIOMED
Beat Rate Control Parameters	ABIOMED
Battery Run Operation Parameters	ABIOMED
Stroke Control Limits	Advanced
UniDirectional Stroke Constants	Implant Only
Valve Unstick Mode	ABIOMED
Initiate Manual Valve Unstick	Clinicians
Test PCE Alarm	Clinicians
Set Hyd. Pr.Offsets	Advanced

Table 5.4 AbioCor Menu Structure (Continued)

Menu Item	Intended Users
View...	
Enter Implant Mode!	Implant Only
Exit Implant Mode!	Implant Only
Enter Home Screen!	Clinicians
Swap Implanted Battery Voltage/Timers!	ABIOMED
Special Functions...	
Logs...	Clinicians
View Implanted Controller Log	ABIOMED
View Console Monitoring Log	Clinicians
Field Service...	ABIOMED
Debug Messages!	ABIOMED
Select Color	ABIOMED
Hide Control Buttons!	Clinicians
Hide Param Popup!	Clinicians

The following pages list and describe all AbioCor Console menu items in alphabetical order. Each listing consists of:

Menu Item — The name of the menu item as it appears on the AbioCor menus.

Menu Path — The sequence of menus needed to access this menu item.

Intended User — Four types of intended users are mentioned:

- ABIOMED: ABIOMED personnel
- Advanced Users: Users with additional training and experience on this menu item.
- Clinicians: Any clinician trained on using the AbioCor System.
- Implant Only: The menu item is used only during implant surgery, and should only be used by persons trained in controlling the AbioCor System during implantation.

Entry Confirmation Box — Notes whether an Entry Confirmation box is displayed before the menu item is activated. (The Entry Confirmation box is only displayed if the user has not entered a menu section requiring confirmation within the last 15 minutes.)

Description — Briefly describes the use of the menu item.

AbioCor Setup...

Menu Path:	Main Menu\AbioCor Setup...
Intended User:	Clinicians
Confirmation Box:	No
Description:	Displays the AbioCor Setup Menu

Alarm Delay

Menu Path:	Main Menu\Console Setup...\Alarm Delay
Intended User:	Clinicians
Confirmation Box:	Yes
Description:	Displays the Alarm Delay Set Popup. When the Console detects a TET misalignment, it triggers an alarm after a short delay. The delay allows for transient misalignments of the TET without causing a barrage of nuisance alarms. This popup sets the delay between a TET misalignment and the alarm.

Alarms...

Menu Path:	Main Menu\Console Setup...\Alarms...
Intended User:	Advanced Users
Confirmation Box:	Yes
Description:	Displays the Alarms Menu, which is used to mask alarms as described in Appendix C.

Automatic Control Parameters...

Menu Path:	Main Menu\AbioCor Setup...\Automatic Control Parameters...
Intended User:	Advanced Users
Confirmation Box:	Yes
Description:	Displays the Automatic Control Parameters Menu

Balance Control Parameters...

Menu Path:	Main Menu\AbioCor Setup...\Automatic Control Parameters...\Balance Control Parameters
Intended User:	ABIOMED
Confirmation Box:	Yes
Description:	Displays the Balance Control Parameters Popup

Battery Run Operation Parameters

Menu Path: Main Menu\AbioCor Setup...\Automatic Control Parameters...\Battery Run Operation Parameters
Intended User: ABIOMED
Confirmation Box: Yes
Description: Displays the Battery Run Operation Parameters Popup

Beat Rate Control Parameters

Menu Path: Main Menu\AbioCor Setup...\Automatic Control Parameters...\Beat Rate Control Parameters
Intended User: ABIOMED
Confirmation Box: Yes
Description: Displays the Beat Rate Control Parameters Popup

Calibrate All Physiologic Inputs

Menu Path: Main Menu\Console Setup...\Console Calibration...\Calibrate All Physiologic Inputs
Intended User: Clinicians
Confirmation Box: No
Description: Displays the Calibrate All Physiologic Inputs Popup. This dialog allows clinicians to calibrate the AbioCor Console for use with patient physiologic monitors. Calibration ensures that the waveforms and values on the AbioCor Console display agree with those shown on the actual physiologic monitors. See Appendix H for more information.

Clear TET Fault Alarm

Menu Path: Main Menu\Console Setup\Clear TET Fault Alarm
Intended User: ABIOMED
Confirmation Box: Yes
Description: Not discussed in this manual

Console Calibration...

Main Menu\Console Setup...\Console Calibration...
Intended User: Clinicians
Confirmation Box: Yes
Description: Displays the Calibrate All Physiologic Inputs and Establish Est. (Estimated) Phy. (Physiologic) Inputs.

Console Setup...

Menu Path:	Main Menu\Console Setup...
Intended User:	Clinicians
Confirmation Box:	No
Description:	Displays the Console Setup Menu.

Console Technical

Menu Path:	Main Menu\Console Setup...\Alarms...\Console Technical
Intended User:	Advanced Users
Confirmation Box:	No
Description:	Displays the Alarm Configuration Popup for Console Technical alarms. This popup allows advanced users to "mask" (disable) alarms. DO NOT MASK ANY ALARMS WITHOUT AUTHORIZATION. Alarm masking can affect patient safety.

Date/Time

Menu Path:	Main Menu\Console Setup...\Date/Time
Intended User:	Clinicians
Confirmation Box:	Yes
Description:	Displays the Date/Time popup, which sets the AbioCor System's internal date/time clock. The AbioCor uses 24-hour (military) time.

Debug Messages!

Menu Path:	Main Menu\Special Functions...\Debug Messages!
Intended User:	ABIOMED
Confirmation Box:	No
Description:	Not discussed in this manual

Enter Home Screen!

Menu Path:	Main Menu\View...\Enter Home Screen!
Intended User:	Clinicians
Confirmation Box:	No
Description:	Switches the AbioCor System to Home Mode.

Enter Implant Mode!

Menu Path:	Main Menu\View...\Enter Implant Mode!
Intended User:	Implant only
Confirmation Box:	Yes
Description:	Switches the AbioCor System to Implant Mode, which is used only during implantation.

Enter Standby Mode!

Menu Path:	Main Menu\Console Setup...\Enter Standby Mode!
Intended User:	Clinicians
Confirmation Box:	Yes
Description:	Switches the AbioCor System to Standby Mode. In Standby Mode, the Console operates at reduced power and does not drive the TET. Standby Mode is intended to reduce noise and confusion when the Console is not in use (e.g., if the patient is using the PCE system), if the Console is acting as a backup, or if no TET is plugged into the Console.

Establish Est. Phy. Inputs

Menu Path:	Main Menu\Console Setup...\Console Calibration...\Establish Est. Phy. Inputs
Intended User:	ABIOMED
Confirmation Box:	No
Description:	Not discussed in this manual

Exit Implant Mode!

Menu Path:	Main Menu\View...\Exit Implant Mode!
Intended User:	Implant only
Confirmation Box:	Yes
Description:	Switches the AbioCor System out of Implant Mode.

Exit Standby Mode!

Menu Path:	Main Menu\Console Setup...\Exit Standby Mode!
Intended User:	Clinicians
Confirmation Box:	No
Description:	Switches the AbioCor System out of Standby Mode.

Field Service...

Menu Path:	Main Menu\Special Functions\Field Service
Intended User:	ABIOMED
Confirmation Box:	No
Description:	Not discussed in this manual

Hide Control Buttons...

Menu Path:	Main Menu\Hide Control Buttons!
Intended User:	Clinicians
Confirmation Box:	No
Description:	Disables the Beat Rate, Balance, and Motor Speed Control soft buttons at the bottom of the display, and removes the button labels from the display.

Hide Param Popup...

Menu Path:	Main Menu\Hide Param Popup!
Intended User:	Clinicians
Confirmation Box:	No
Description:	Removes the Param Popup Dialog from the display. Pressing the Cancel button when the Param Popup display is shown has the same effect. For more information refer to Param Popups earlier in this section.

IC Battery Timer Delay Startup

Menu Path:	Main Menu\Console Setup...\IC Battery Timer Delay Startup
Intended User:	ABIOMED
Confirmation Box:	Yes
Description:	Not discussed in this manual

Implanted Controller Technical

Menu Path:	Main Menu\Console Setup...\Alarms...\Implanted Controller Technical
Intended User:	Advanced Users
Confirmation Box:	No
Description:	Displays the Alarm Configuration Popup for Implanted Controller Technical alarms. This popup allows advanced users to "mask" (disable) alarms. DO NOT MASK ANY ALARMS WITHOUT AUTHORIZATION. Alarm masking can affect patient safety.

Initiate Manual Valve Unstick

Menu Path:	Main Menu\AbioCor Setup...\Initiate Manual Valve Unstick
Intended User:	ABIOMED
Confirmation Box:	Yes
Description:	Not discussed in this manual

Input Beat Rate Range

Menu Path:	Main Menu\Console Setup...\Input Beat Rate Range
Intended User:	Clinicians
Confirmation Box:	No
Description:	Displays the Input Beat Rate Range popup, which is used to set limits on the range of allowed beat rates. It affects both Home Mode and Clinical Mode.

Input Phone Numbers

Menu Path:	Main Menu\Console Setup...\Input Phone Numbers
Intended User:	Clinicians
Confirmation Box:	Yes
Description:	Displays the Input Phone Numbers popup. The Home Mode screen displays emergency contact telephone numbers as part of some alarm messages. This popup dialog allows clinicians to enter emergency contact numbers for the patient's local care provider and for ABIOMED. In the Input Phone number dialog, the Selector Knob works one digit at a time.

Log Only Alarms

Menu Path:	Main Menu\Console Setup...\Alarms...\Log Only Alarms
Intended User:	Advanced Users
Confirmation Box:	
Description:	Displays the Alarm Configuration Popup for Log Only alarms. This popup allows advanced users to "mask" (disable) alarms. DO NOT MASK ANY ALARMS WITHOUT AUTHORIZATION. Alarm masking can affect patient safety.

Logs...

Menu Path:	Main Menu\Special Functions\Logs...
Intended User:	Clinicians
Confirmation Box:	No
Description:	Displays the Logs menu

Patient ID

Menu Path:	Main Menu\Console Setup...\Patient ID
Intended User:	Clinicians
Confirmation Box:	Yes
Description:	Displays the Patient ID popup dialog, which is used to enter an ID number for the AbioCor patient. The ID number (which must contain 10 digits) is used by ABIOMED to aid in analyzing and evaluating AbioCor performance data. This number is attached to all Log and Data Capture files generated by the Console and transmitted to ABIOMED.

Physiologic/Control

Menu Path:	Main Menu\Console Setup...\Alarms...\Physiologic/Control
Intended User:	Advanced Users
Confirmation Box:	No
Description:	Displays the Alarm Configuration Popup for Physiologic/Control alarms. This popup allows advanced users to "mask" (disable) alarms. DO NOT MASK ANY ALARMS WITHOUT AUTHORIZATION. Alarm masking can affect patient safety.

Power Console

Menu Path:	Main Menu\Console Setup...\Alarms...\Power Console
Intended User:	Advanced Users
Confirmation Box:	No
Description:	Displays the Alarm Configuration Popup for Console Power alarms. This popup allows advanced users to "mask" (disable) alarms. DO NOT MASK ANY ALARMS WITHOUT AUTHORIZATION. Alarm masking can affect patient safety.

Power Controller

Menu Path: Main Menu\Console Setup...\Alarms...\Power Controller
Intended User: Advanced Users
Confirmation Box: No
Description: Displays the Alarm Configuration Popup for Controller Power alarms. This popup allows advanced users to "mask" (disable) alarms. DO NOT MASK ANY ALARMS WITHOUT AUTHORIZATION. Alarm masking can affect patient safety.

Pump Technical

Menu Path: Main Menu\Console Setup...\Alarms...\Pump Technical
Intended User: Advanced Users
Confirmation Box: No
Description: Displays the Alarm Configuration Popup for Pump Technical alarms. This popup allows advanced users to "mask" (disable) alarms. DO NOT MASK ANY ALARMS WITHOUT AUTHORIZATION. Alarm masking can affect patient safety.

RF/TET Channel Mode Selection

Menu Path: Main Menu\Console Setup...\RF/TET Channel Mode Selection
Intended User: Clinicians
Confirmation Box: Yes
Description: Displays the RF/TET Channel Mode Selection popup. See Section 3 and earlier portions of Section 6 for more information on the RF and TET Channels.

RF Telemetry

Menu Path: Main Menu\Console Setup...\Alarms...\RF Telemetry
Intended User: Advanced Users
Confirmation Box: No
Description: Displays the Alarm Configuration Popup for RF Telemetry alarms. This popup allows advanced users to "mask" (disable) alarms. DO NOT MASK ANY ALARMS WITHOUT AUTHORIZATION. Alarm masking can affect patient safety.

Select Color

Menu Path:	Main Menu\Special Functions...\Select Color
Intended User:	ABIOMED
Confirmation Box:	No
Description:	Not discussed in this manual

Select Controller

Menu Path:	Main Menu\AbioCor Setup...\Select Controller
Intended User:	Clinician
Confirmation Box:	Yes
Description:	Displays the Select Controller popup, which is used while setting up a Console for a new patient. This dialog causes the Console to read and save the ID number of the patient's implanted controller from the controller. See Appendix C for more information.

Set Hyd. Pr. Offsets

Menu Path:	Main Menu\AbioCor Setup...\Set Hyd. Pr. Offsets
Intended User:	Advanced
Confirmation Box:	Yes
Description:	Displays the Set Hydraulic Pressure Offset popup, which allows the user to calibrate the offsets for the Left and Right Hydraulic Pressure (LHP and RHP) transducers.

Setup FTP

Menu Path:	Main Menu\Console Setup...\Setup FTP
Intended User:	Clinicians
Confirmation Box:	No
Description:	Displays the Setup FTP Dialog, which is used to configure the Console for networking, data communications, and remote monitoring by ABIOMED. See Appendix D for more information.

Show Control Buttons!

Menu Path: Main Menu\Show Control Buttons!
Intended User: Clinicians
Confirmation Box: No
Description: Displays the labels for the Beat Rate, Balance, LMS, and RMS control soft buttons. The buttons will not work unless the labels are displayed. See Section 6 for more information on using these controls.

Show Param Popup!

Menu Path: Main Menu\Show Param Popup!
Intended User: Clinicians
Confirmation Box: No
Description: Displays the Parameter popup dialog, discussed earlier in this Section. The Parameter dialog provides detailed information on the AbioCor System's power and communications status.

Special Functions...

Menu Path: Main Menu\Special Functions...
Intended User: Clinicians
Confirmation Box: No
Description: Displays the Special Functions menu.

Start Data Capture!

Menu Path: Main Menu\Start Data Capture!
Intended User: Clinician
Confirmation Box: No
Description: The Data Capture function saves a 4-minute long snapshot of all the data collected by the AbioCor System. The snapshot begins two minutes before Data Capture was started and ends two minutes afterward.

Typically, a clinician would activate Data Capture to record unusual or abnormal waveforms or AbioCor System behavior for later review and analysis. The snapshot can be retrieved by an ABIOMED engineer or by remote data communications.

Stroke Control Limits

Menu Path:	Main Menu\AbioCor Setup...\Automatic Control Parameters...\Stroke Control Limits
Intended User:	Advanced
Confirmation Box:	Yes
Description:	Displays the Stroke Control Limits popup. This allows advanced users to set the limits for the left and right motor speeds, and is usually used in consultation with ABIOMED for situations where repeated overstroking or understroking alarms cannot be controlled by medical means. See Section 6 for more information.

Stroke Control Parameters

Menu Path:	Main Menu\AbioCor Setup...\Automatic Control Parameters...\Stroke Control Parameters
Intended User:	ABIOMED
Confirmation Box:	Yes
Description:	Not discussed in this manual

Swap Implanted Battery Voltage/Timers

Menu Path:	Main Menu\View...\Swap Implanted Battery Voltage/Timers!
Intended User:	ABIOMED
Confirmation Box:	Yes
Description:	Not discussed in this manual

PCE

Menu Path:	Main Menu\AbioCor Setup...\Test PCE Alarm
Intended User:	Clinician
Confirmation Box:	No
Description:	Tests alarm communications between the Implanted Controller and the PCE. It causes the Implanted Controller to trigger an alarm on the TET channel, which should be detected and displayed on the PCE. See Appendix A and the PCE manual for more information.

Unidirectional Stroke Constants

Menu Path:	Main Menu\AbioCor Setup...\Automatic Control Parameters...\UniDirectional Stroke Constants
Intended User:	Implant Only
Confirmation Box:	Yes
Description:	Not discussed in this manual

Valve Unstick Mode

Menu Path:	Main Menu\AbioCor Setup...\Automatic Control Parameters...\Valve Unstick Mode
Intended User:	ABIOMED
Confirmation Box:	Yes
Description:	Not discussed in this manual

View Console Monitoring Log

Menu Path:	Main Menu\Special Functions...\Logs...\View Console Monitoring Log
Intended User:	Clinicians
Confirmation Box:	No
Description:	The Console log stores a history of all AbioCor events (alarms and setting changes) for approximately one week. This menu item allows clinicians to review this log.

View Implanted Controller Log

Menu Path:	Main Menu\Special Functions...\Logs...\View Implanted Controller Log
Intended User:	ABIOMED
Confirmation Box:	No
Description:	Not discussed in this manual

View...

Menu Path:	Main Menu\View...
Intended User:	Clinicians
Confirmation Box:	No
Description:	Displays the View menu.

Waveform Selection

Menu Path:	Main Menu\Console Setup...\Waveform Selection
Intended User:	ABIOMED
Confirmation Box:	Yes
Description:	Not discussed in this manual

Clinical Mode Settings that Affect the Home Screen

Table 5.5 lists the Clinical Mode settings that affect the Home Screen, and describes their effects.

Table 5.5 Clinical Mode Settings that Affect the Home Screen

Clinical Mode Setting	Effect on Home Screen
Beat Rate	This is the same as the Heart Rate (HR) control on the Home Screen. Changes to the Beat Rate setting in Clinical Mode will appear as changes to the Heart Rate control on the Home Screen.
Balance	This is the same as the Left Heart Pressure (LHP) control on the Home Screen. Changes to the Balance setting in Clinical Mode will appear as changes to the LAP control on the Home Screen.
Input Phone Numbers	This popup sets the phone numbers that appear in Home Screen alarm messages.
Input Beat Rate Range	This popup sets the range of allowed Heart Rate settings for both the Clinical and Home screens. On the Home Screen, the scale in the Heart Rate panel shows only the allowed settings.

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6 Managing an Implanted AbioCor System

Contents

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Overview

This section covers the information required to manage an AbioCor System that is implanted in a patient. The key areas are:

- Power management

  Ensures that the AbioCor System always has sufficient power to operate the Thoracic Unit and maintain the patient's circulation.

- TET management

  Ensures that the External TET is properly aligned and not causing TET heating or thermal injury.

- Communications management

  Ensures that the AbioCor implanted components can communicate with the external components to transmit alarms, status information, and commands.

- Hemodynamic management

  Ensures that the patient's hemodynamics remain within physiologically acceptable ranges.

- How, When, and Why to Change Beat Rate, Balance, and Motor Speed

  These settings control the operation of the Thoracic Unit, and are critical in managing the patient's hemodynamics.

Power Management

Maintaining power to the AbioCor System implanted components is essential. Without external power, the Implanted Battery will discharge. If the Implanted Battery is ever completely discharged and no external power is available, the implanted heart will stop.

In normal operation, the AbioCor Console gets power from an AC wall outlet and transmits power to the Implantable Components through the TET. The AbioCor System has several backup power sources: a battery built in to the Console (approximately 40 minutes of charge), the Implanted Battery (at least 30 minutes of charge), and the PCE. The Console should be run from an AC wall outlet whenever possible to keep the backup batteries fully charged.

Power management when using the Console includes three elements:

- Console Power
- TET power transmission
- Implanted Battery Power

Figure 6.1 shows the locations of power management information in the Clinical Mode Main screen. The Parameter Window, discussed and illustrated in Section 5, also displays power management information.

In Home Mode, power information is shown in the power panel. See Appendix B for a summary of the Home Mode and related screens, and the Patient Manual for detailed information.

Console Power

The Console is the primary power source for the AbioCor System when patients are in the ICU. As patients recover from implant surgery, stabilize, and become more mobile, the Patient-Carried Electronics (PCE) system is used more often as a primary power source. (The PCE is described in Appendix A as well as in a separate PCE manual.)

The Console draws power from an AC wall outlet or from the battery included in the Console and sends power to the External TET, which sends it to the implanted system. If the Console is plugged in and the wall outlet has power, the Console runs from the AC outlet while simultaneously charging the Console battery to keep it fully charged. The Console automatically switches to battery power if AC power is

lost. The battery is designed to operate the system for approximately 40 minutes, enough time for in-hospital patient transport.

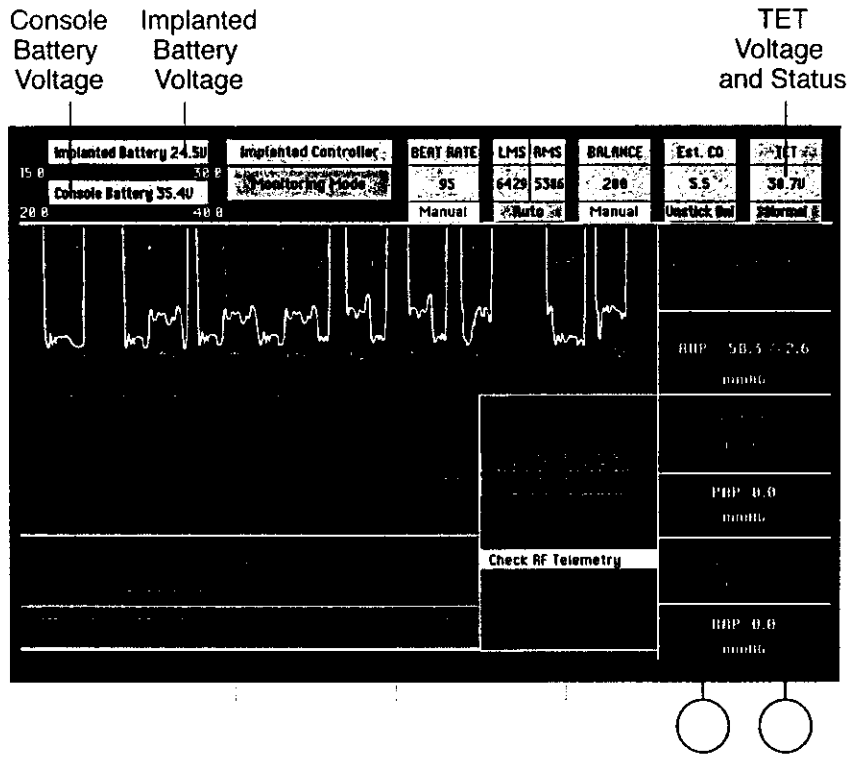

Figure 6.1 Power Information on the AbioCor Clinical Mode Main Screen

The Console battery voltage indicator on the Clinical Mode Main Screen shows the current charge level of the Console Battery.

TET misalignment alarms

TET misalignment is a common AbioCor alarm. To correct TET misalignment, reposition the External TET directly over the Implanted TET.

TET Power Transmission

To properly transmit power through the patient's skin, the Implanted and External TET coils must be close together and properly aligned. TET misalignment is a common cause of AbioCor System alarms. If this occurs, reposition the External TET directly over the Implanted TET. The alarm should end, and the TET status display should return to normal.

The TET voltage and status display shows the current TET voltage and status. Use these displays when positioning the TET.

Heat resulting from the TET system could cause swelling, fluid accumulation, or thermal injury around the Implanted TET. The TET is more likely to produce excess heat when it is poorly aligned.

As discussed in TET Management, the area around the TET should be assessed for swelling or fluid accumulation by daily physical examination.

Implanted Battery Power

The Implanted Battery acts as a backup power source for use if external power is lost and when changing between external power sources. If external power is not available, the AbioCor System automatically switches to the Implanted Battery. It also sets a low beat rate to minimize power consumption. In normal operation, the AbioCor implanted components get power from the Console via the TET, while simultaneously charging the Implanted Battery to keep it fully charged.

The Implanted Battery voltage indicator on the Clinical Mode Main Screen shows the current charge level of the Implanted Battery.

Implanted Battery Voltage

Always ensure the Implanted Battery voltage is at least 23 V before removing the TET.

Checking the Implanted Battery Life

The lifetime of the Implanted Battery should be checked monthly in the hospital. To check it:

1. Ensure that the Implanted Battery voltage is at least 24.5 V.
2. Remove the TET and unplug it from the Console.
3. Ensure that the system can run from the Implanted Battery for at least 30 minutes without triggering a Low Implanted Battery alarm.

If a battery alarm occurs in less than 30 minutes, surgical replacement should be considered.

Implanted Battery Power and the Beat Rate

When the AbioCor System is operating on Implanted Battery power, the beat rate is decreased to 100 bpm if it is not already below 100 bpm. This conserves power to maximize the Implanted Battery life.

Communications Management

There are two modes for handling AbioCor communications:

- RF Channel Mode
- TET Channel Mode

Each communications mode uses the two communications channels—RF Channel and TET Channel—in different ways.

RF Channel Mode vs TET Channel Mode

RF communications are on in both modes. The difference is that, in TET Channel Mode, the AbioCor System does not sound audible alarms due to RF Communications problems.

RF Channel Mode uses the RF Channel all the time, with the TET Channel as a backup. It sounds an audible alarm for any alarm condition, including RF communications problems. The key aspects of RF Channel Mode are:

- It allows quicker detection of problems and response to alarms, because the RF Channel is already established.
- It is more likely to cause nuisance alarms due to RF Communications problems.
- It is usually used all the time in the ICU, and less frequently as the patient recovers, stabilizes, and gains mobility.

RF Communications

The AbioCor System cannot receive commands or give detailed information on alarms or the system status without RF communications.

TET Channel Mode uses the TET Channel all the time, and the RF Channel when RF communications are available. It does not sound an audible alarm for RF communications problems, but does sound an alarm for all other alarm conditions. The key aspects of RF Channel Mode are:

- It slows response to alarms because the RF Channel needs to be established to determine the type of alarm, assess patient hemodynamics, or adjust the AbioCor settings.
- It eliminates nuisance alarms due to RF Communications problems.
- It is used increasingly as the patient recovers, stabilizes, and gains mobility.
- It is the usual operating mode in the home environment and when using the PCE.

The communications mode is selected in the RF Channel/TET Channel Alarm Popup, reached from the Console Setup menu.

Managing RF Communications

When using the RF Channel Mode, maintaining good RF signal quality is necessary to minimize nuisance alarms and maintain a steady flow of diagnostic information. The key to RF signal quality is correctly positioning the RF Communications Module, which should be kept on the patient's abdomen just above the Implanted Controller. When positioning the RF Communications Module, take care to ensure that the RF Communications cable does not become kinked.

In Clinical Mode, RF signal quality is shown in the Patient --> Console Comm Status and Console --> Patient Comm Status areas of the Parameter Window, as shown in Figure 6.2. The Parameter popup is discussed in more detail in Section 5. These displays can be used to guide the positioning of the RF Communications module. If the module is poorly positioned, these displays show mostly "o", indicating poor signal quality. As the RF Module is moved into a better position, ">" signs indicating good signal quality will move in from the left. The signal quality is good when the display shows all ">". Table 6.1 shows typical Comm Status displays with different signal quality.

Viewing the Parameter Window

In Clinical Mode, the Parameter window shows RF signal quality. To show it, select "Show Param Window" in the Main Menu.

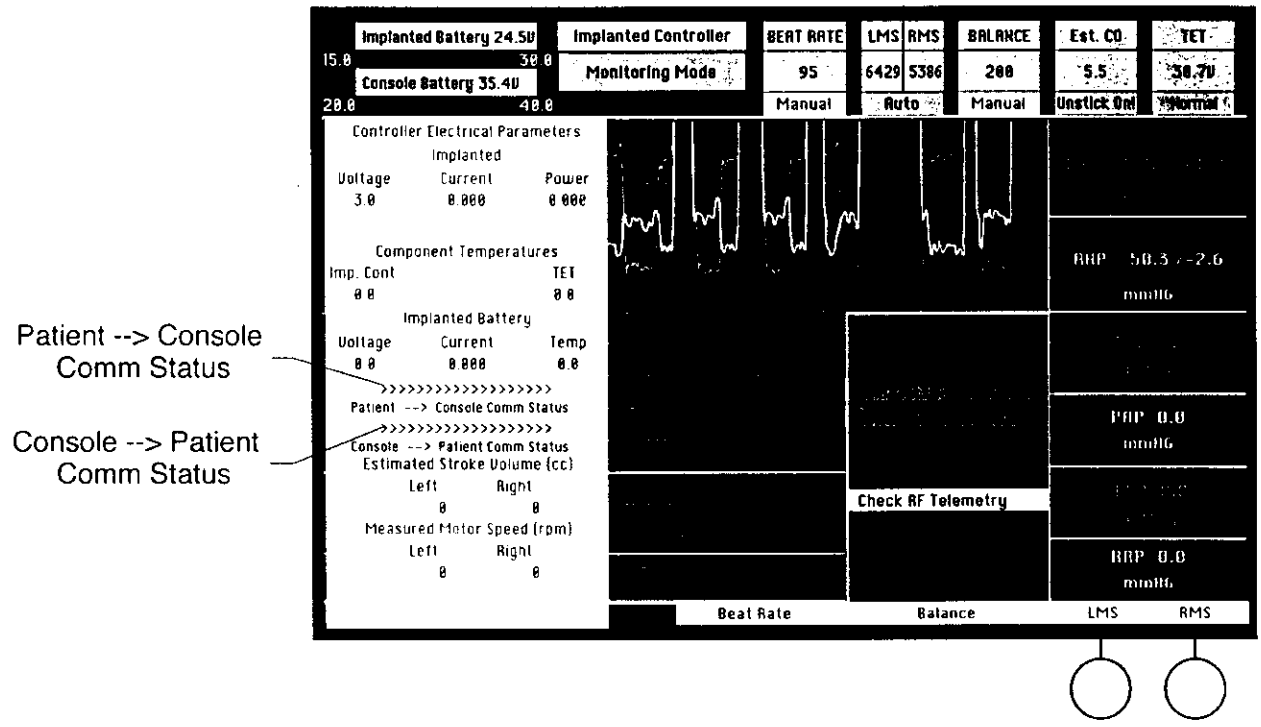

Figure 6.2 RF Communications Information on the Clinical Mode Parameter Screen

Table 6.1 RF Signal Quality Examples

Signal Quality	Typical Comm Status Display
Poor	ooo>ooooo>>oooooooo
Improving	>>>oo>>o>>ooo>o>ooo
Good	>>>>>>>>>>>>>>>>>>>

RF signal quality also is shown on the Home screen in the RF panel, as summarized in Appendix B and discussed in detail in the Patient Manual.

Problems with RF communications probably result from poor positioning of the RF Communications module, as discussed above. Other possible causes include electrical interference and RF Communications Module failures.

Electrical Interference

Electrical interference from external devices should be managed by removing or turning off the offending device. Problem devices can be identified by turning each suspected device off one at a time and checking whether the interference goes away.

Avoid having two different external AbioCor RF communications systems working near each other at the same time (e.g., two RF Communications modules or a RF Communications Module and a Handheld Monitor from the PCE system). Transmissions from the two modules will interfere with each other.

RF Communications Module Failure

To replace the RF Communications Module, unscrew its connector from the Console, plug in the new module, and position the new module. Communications will start automatically.

TET Management

The External TET needs to be correctly aligned with the Implanted TET to ensure good coupling and efficient power transmission. A poorly aligned TET can cause thermal injury and swelling and may lead to a dangerous and difficult to manage condition. The TET area should be physically examined each day to check for swelling and fluid buildup.

Aligning the TET

TET misalignment is a common cause of AbioCor alarms. To correct TET misalignment, reposition the External TET directly over the Implanted TET. Use the TET Voltage display on the Clinical Main Screen as an aid in positioning the TET. The Console will indicate "Normal" when the External TET and Implanted TET are properly aligned.

Avoid pulling on the TET cable. To help avoid accidental strain on the cable, keep it out of bed covers. Do not let the patient lie on it.

It is normal for the TET cable to become warm. If the cable becomes *HOT*, replace the External TET coil.

Managing the TET Area

The External TET must be positioned directly above the Implanted TET and against the skin for good power transmission. Immediately after surgery, a black fabric pouch is used to position the TET. This should be removed and replaced with a DuoDerm patch after 3 or 4 days. The TET is held to the patch with Velcro loops. The DuoDerm patch should be changed every 3 or 4 days.

Poor alignment or high power operation (usually caused by a high beat rate) can cause heating around the TET, leading to patient discomfort or thermal injury. High temperatures can be corrected by realigning the TET and/or decreasing the implanted system's power use (usually by decreasing the beat rate).

To prevent this situation, examine the TET area daily for swelling or fluid buildup. If fluid buildup is found, it may be necessary to remove the excess fluid by needle aspiration. Take care not to damage the Implanted TET cable when aspirating.

One possible short term measure to manage fluid buildup around the TET is to lay a full 1 liter IV bag on top of the External TET. This may push it closer to the Implanted TET and improve the alignment until an intervention can be done.

Hemodynamic Management

The ultimate goal of an AbioCor System is to produce and maintain normal hemodynamics. Because the AbioCor System simulates many aspects of natural heart function, the principles of hemodynamic monitoring and cardiovascular management for the AbioCor System are similar in most respects to those for a natural heart. The key factors that influence hemodynamics in a patient with an implanted AbioCor System are generally related to either the AbioCor System or the patient.

AbioCor System factors that can influence hemodynamics include:

- Beat Rate
- Left and Right Motor Speed
- Balance Setting

How, when, and why to change these factors is discussed later in this Section.

Patient factors that can influence hemodynamics include:

- Inflow pressures
- Afterload pressures
- Vascular compliance

To aid in maintaining normal hemodynamics, the AbioCor Console constantly measures, displays, and logs key data related to patient hemodynamics, including:

- Estimated Cardiac Output
- Left Hydraulic Pressure (LHP)
- Right Hydraulic Pressure (RHP)

Left hydraulic pressure (LHP) and right hydraulic pressure (RHP) values represent the pressure in mm Hg of the hydraulic fluid on the left and right sides of the Energy Converter, and are measured by pressure transducers in the Energy Converter.

Although there is a relationship between LHP, RHP and the corresponding blood pressures, they are *not* equal. The relationship varies for different operating conditions, AbioCor Systems, and patients.

Determining the details of the relationships for a particular patient requires observation of the patient over time. In general, an increase or decrease in the AbioCor hydraulic pressure reflects an increase or decrease in the corresponding blood pressure, as listed in Table 6.2.

Table 6.2 AbioCor Hydraulic Pressure Measurements and Related Blood Pressure Values

AbioCor Hydraulic Pressure Measurement	Related Blood Pressure
Systolic LHP (sLHP)	Mean Aortic Pressure (MAP)
Diastolic LHP (dLHP)	Left Atrial Pressure (LAP)
Systolic RHP (sRHP)	Pulmonary Arterial Pressure (PAP)
Diastolic LHP (dLHP)	Central Venous Pressure (CVP)

Hydraulic Pressure Waveforms

To aid in monitoring the AbioCor System and the patient, the Clinical Mode main screen shows a real-time graphical display of moment-to-moment values of the LHP and RHP for the last XX seconds. These graphs, known as waveforms, are useful tools for assessing the AbioCor System's hemodynamic performance. A knowledgeable and experienced clinician can use these tools in combination with other available information to diagnose most AbioCor hemodynamic problems, including all common problems.

Normal Hemodynamics

Figure 6.3 shows normal RHP and LHP waveforms.

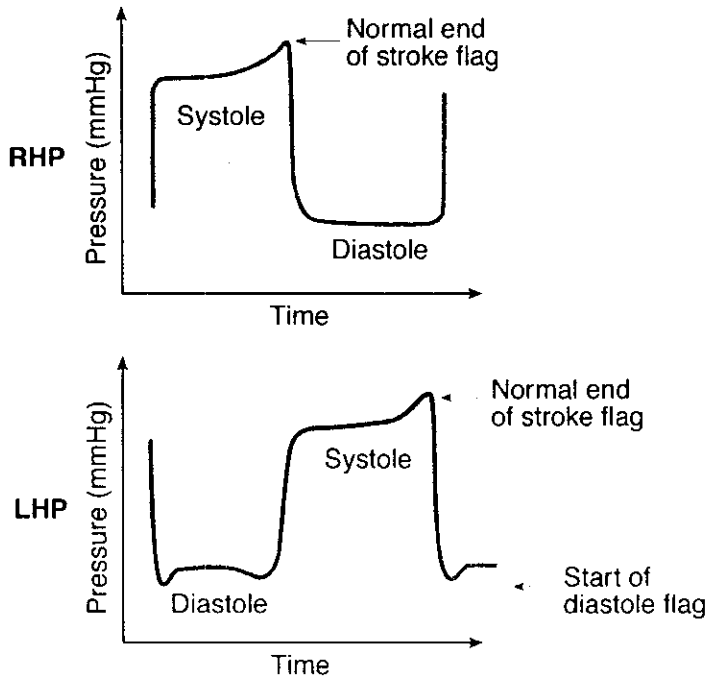

Figure 6.3 Normal RHP and LHP Waveforms

The waveforms illustrate several significant points:

- The left blood pump is in systole when the right blood pump is in diastole, and vice versa.
- Each systole should end in a small positive peak, known as the end of stroke flag.

Abnormal Hemodynamic Waveforms

Analysis of the LHP and RHP waveforms can aid in diagnosing several common problems, listed in Table 6.3. Each of these problems will trigger an AbioCor alarm if it occurs.

Table 6.3 Common Hemodynamic Problems Related to the AbioCor System

Problem	Hydraulic Pressure Characteristics
Inflow limiting	Large negative end-of-fill flag No end-of-stroke flag, and the end-of-stroke waveform is rounded and gradual
Overstroking	End-of-stroke flag too large
Understroking	End-of-stroke flag too small

Table 6.4 lists the waveform characteristics that suggest each of these problems. Each problem is discussed in more detail on the following pages.

Table 6.4 AbioCor Hydraulic Waveform Characteristics and Possible Causes

Waveform Characteristics	AbioCor Problem	Possible Root Cause
End-of-stroke flag too large	Overstroking	Hypotension
End-of-stroke flag too small	Understroking	Hypertension
End-of-stroke flag absent Waveform is rounded and gradual at the end-of-stroke Large negative flag at end-of-fill	Inflow limiting	Not enough blood in the atrium, due to: Poor posture Atrial or blood vessel compression or collapse Atrial collapse ("suck down") Hypovolemia Tamponade Excessive PEEP pressure

Inflow limiting

Inflow limiting occurs when there is not enough blood in the left or right atrium to fill the Left or Right Blood Pump. It can occur on either or both sides of the Thoracic Unit. Figure 6.4 shows waveforms typical of inflow limiting.

WARNING: Inflow limiting is a possibly life-threatening condition.

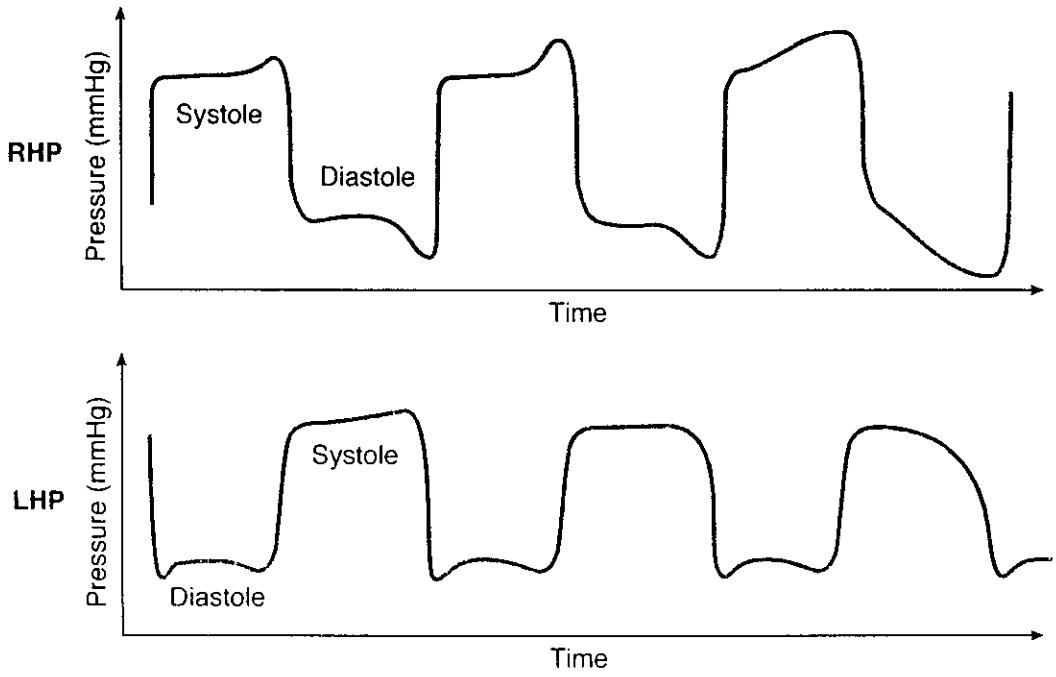

Figure 6.4 Right Inflow Limiting: Characteristic LHP and RHP Waveforms

Tamponade

Tamponade is associated with internal bleeding around the atria. When it occurs, it usually happens soon after implantation, as an adverse effect of the surgery. In tamponade, blood pooling may compress the atrium and prevent the atrium from filling and therefore the associated blood pump from filling.

On the AbioCor System, tamponade appears as inflow limiting with normal or high atrial pressure. Inflow limiting due to other conditions is generally associated with low atrial pressure.

Tamponade is a medical emergency that may require surgical treatment.

AbioCor Signs	Prominent negative flags (pressure peaks) at the end of diastole on the side with inflow limiting Changes in the LHP and RHP waveform as shown in Figure 6.4
Other Signs	Marked decreases in LAP or RAP
Possible Causes	Poor posture Compression or collapse of blood vessels that return blood to the atria Atrial collapse ("suck down") Hypovolemia typically causes inflow limiting on both sides, as discussed in Section 7. Tamponade causes inflow limiting without low atrial pressure. See sidebar. Positive end expiratory pressure ventilation (PEEP) pressure greater than 5 cm H_2O.
Possible Corrective Actions	The AbioCor System will automatically decrease the motor speed on the side opposite the inflow limiting, which will decrease the patient's blood pressure and cardiac output. Normal operation will resume when the condition is resolved. Adjust the patient's posture. The patient should lie down in the Trendelenberg position. Give volume. For left inflow limiting, increase the balance setting. For right inflow limiting, decrease the beat rate.

Low Flow Alarms and Inflow Limiting

A low flow alarm indicates that the AbioCor System's cardiac output is too low. Low flow can be a life threatening condition. It is usually caused by severe inflow limiting, and should initially be handled like inflow limiting.

If corrective actions for inflow limiting do not resolve a low flow alarm, the problem may lie in the AbioCor System. Contact ABIOMED for assistance.

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Overstroking

Overstroking occurs when the stroke volume in either blood pump is larger than it should be. The AbioCor automatically controls motor speeds to prevent overstroking. Manual correction of overstroking is rarely necessary except during implantation, and should only be performed by advanced users or in consultation with ABIOMED. Figure 6.5 shows waveforms typical of overstroking.

PRECAUTION: Overstroking increases wear on the membrane and may decrease the life of the AbioCor System.

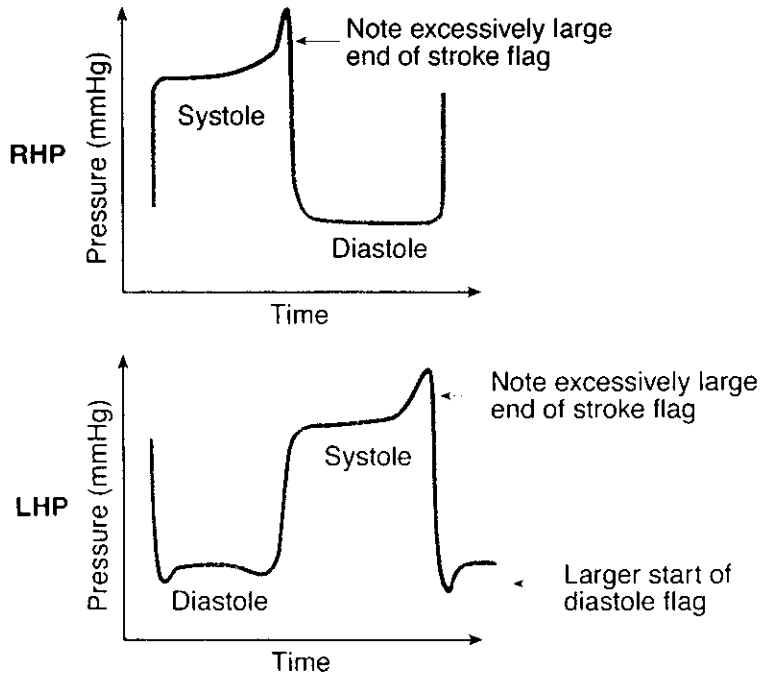


Figure 6.5 Overstroking: Characteristic LHP and RHP Waveforms

End of Stroke Flag and Motor Speeds

The AbioCor Implanted Controller uses the end of stroke flag on each side to automatically set the motor speed on that side. A part of the Implanted Controller software known as the "Full Stroke Control algorithm" increases the motor speed if the flag is too small, and decreases it if the flag is too large.

In most conditions, this automatic control prevents overstroking and understroking. These conditions are rare except during implantation.

AbioCor Signs	Excessively large positive flags (pressure spikes) at the end of systole, as shown in Figure 6.5
Possible Causes	Severely reduced afterload pressure Hypotension
Possible Corrective Actions	Consider use of vasoconstrictor medications if the low afterload is due to hypotension For persistent overstroking, it may be necessary to change the motor speed limits to allow lower motor speeds. The motor speed limits should only be changed by advanced users or in consultation with ABIOMED.

Understroking

Understroking occurs when the stroke volume in either blood pump is smaller than it should be. As with overstroking, the AbioCor automatically controls motor speeds to prevent understroking, and manual correction of overstroking is rarely needed. Figure 6.6 shows waveforms typical of understroking.

Understroking is not hazardous, but it may affect the AbioCor System's ability to adjust the Thoracic Unit's operation for changing conditions.

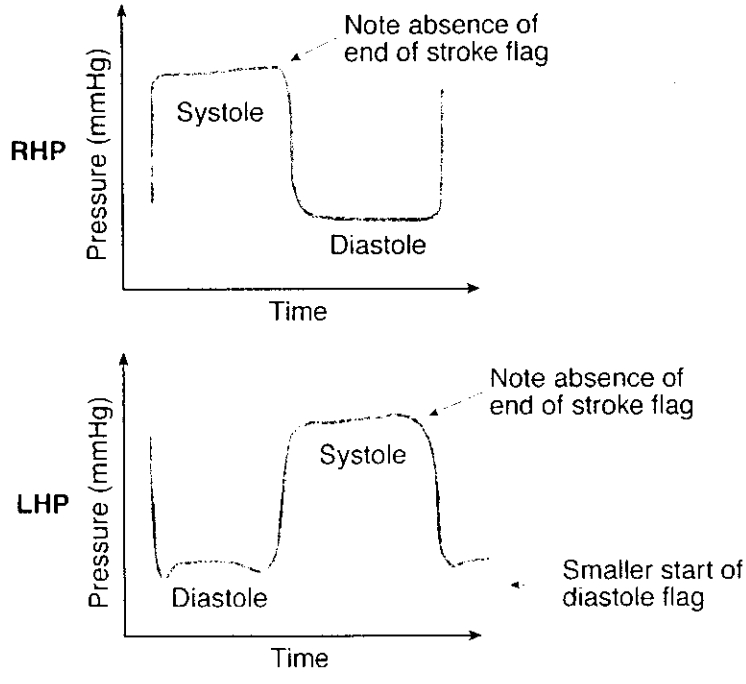


Figure 6.6 Understroking: Characteristic LHP and RHP Waveforms

AbioCor Signs	No pressure spike at the end of systole, as shown in Figure 6.6.
Possible Causes	High afterload pressure Hypertension
Possible Corrective Actions	Ensure that the missing flag is not due to inflow limiting Consider using vasodilators if hypertension is present For persistent understroking, it may be necessary to change the motor speed limits to allow higher motor speeds. The motor speed limits should only be changed by advanced users or in consultation with ABIOMED.

How, When, and Why to Change Thoracic Unit Settings

Many hemodynamic problems can be addressed by changing the Thoracic Unit settings: beat rate, balance, left motor speed, and right motor speed. However, before changing any settings, clinicians should review all the available information on the patient's condition and determine whether the problem should be managed with the AbioCor System, a medical treatment, or both.

This section gives a detailed description of the procedure for changing these parameters, followed by a discussion of hemodynamic conditions that might indicate the need for a change.

To Change Thoracic Unit Settings: Short Version

1. Show the Control Buttons using the Main Menu.
2. Press the appropriate button.
3. Turn the Selector Knob to select the desired setting.
4. Press the Selector Knob.
5. Confirm the change.
6. Monitor the patient's condition.

How to Change the Beat Rate, Balance, or Motor Speed

The Control Button labels must be showing to enable the controls.

Your Action	AbioCor Console Response
1. Press the Menu button.	The Main Menu appears, as shown in Figure 6.7.
2. Rotate the Selector Knob to highlight the "Show Control Buttons!" item.	
3. Press the Selector Knob.	The Main Menu disappears, and the Control Button labels appear at the bottom of the screen, as shown in Figure 6.8
4. Press the soft button for the setting you wish to change: Beat rate, Balance, LMS, or RMS	The Control Button label will change to show the current value of the setting on a green background, as shown in Figure 6.9.
5. Rotate the Selector Knob until the Control Button label displays the desired setting. Rotate the knob clockwise to increase the setting, counterclockwise to decrease it.	The value changes as the knob rotates, and the button label background color changes to yellow, as shown in Figure 6.10.
6. Press the Selector Knob.	The button label background color changes back to green. The Console sends the new setting to the Implanted Controller.
7. Confirm that the new setting has actually taken effect by watching the status bar. The actual value should equal the set value within 10 seconds.	
8. Monitor the patient's condition and hemodynamics to ensure that the setting change has the desired effect.	

The LMS and RMS settings change with every heart beat, and these changes will be shown in the Control Button label.

Press the cancel key to cancel your changes and return to the original setting.

To put the motor speed control into automatic mode, rotate the knob clockwise until the Control Button label reads "Auto"

If the value doesn't change, check RF communications. Contact ABIOMED if this does not resolve the problem.

Figure 6.7 Clinical Main Menu Screen

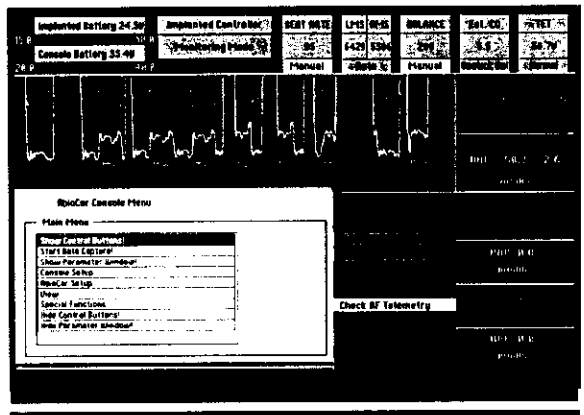


Figure 6.8 Clinical Screen with Control Buttons Shown

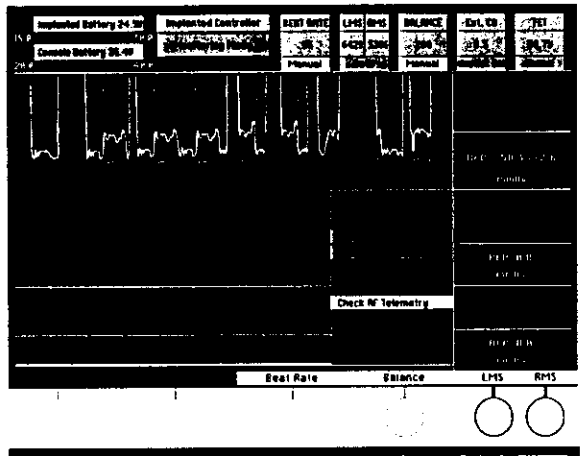


Figure 6.9 Clinical Screen with Beat Rate Buttons Active

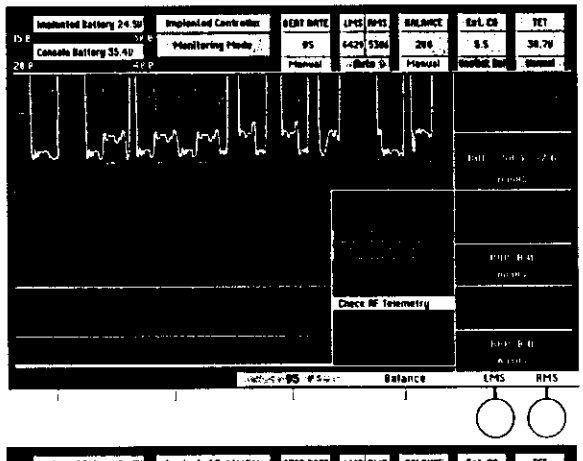
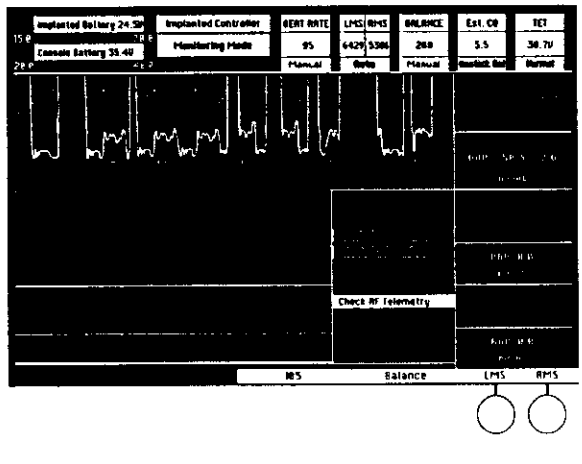


Figure 6.10 Clinical Screen with Beat Rate Being Changed



When and Why to Change Beat Rate, Balance, and Motor Speed

Beat Rate

The beat rate can be varied between 85 and 150 beats per minute (bpm).

Increasing the beat rate tends to:

- Increase cardiac output
- Decrease Right Atrial Pressure (RAP)
- Decrease filling of the Right Blood Pump

Effects of High RAP

RAP should be maintained between 10-15 mm Hg. High RAP can cause liver function problems.

Reasons to *increase* the beat rate include:

- High activity levels
- High RAP

Decreasing the beat rate will decrease cardiac output and blood pressure. Consider the patient's ability to tolerate these changes before decreasing the beat rate.

Reasons to *decrease* the beat rate include:

- Relaxation or sleep
- Right inflow limiting
- Hypovolemia

Balance

Effects of High LAP

LAP should be maintained between 10-15 mm Hg. High LAP can cause respiratory problems, including pulmonary congestion or edema.

The balance setting can vary between 0 (occluder valve fully open, minimum LAP) and 400 (occluder valve fully closed, maximum LAP).

Increasing the balance tends to increase LAP. Reasons to *increase* balance include:

- Left inflow limiting

Reasons to *decrease* balance include:

- High LAP

Balance and Cardiac Output

Increasing the balance setting to greater than about 250 can reduce flow by as much as 20%.

When and Why to Change Left and Right Motor Speeds

The left and right motor speeds are usually controlled automatically. Manual motor speed control is not recommended except during implantation. When the motor speed is in manual control, a trained clinician should monitor the patient's condition and hemodynamics and adjust the motor speed accordingly.

Changing To and From Automatic Motor Speed Control

To change to automatic motor speed control:
1. Show the Control Buttons using the Main Menu
2. Press the left or right motor speed button.
3. Turn the Selector Knob clockwise until the motor speed button reads "Auto".
4. Press the Selector Knob.
5. Confirm the change.
6. Monitor the patient's condition.

Note: Automatic motor control cannot be activated if there are any active alarms, or if the cardiac output is less than 3 lpm.

Manual motor speed control is activated whenever a numeric value is selected for the motor speed.

In situations where persistent overstroking or understroking must be managed using the motor speed control, the motor speed limits can be changed. Motor speed limits should only be changed by advanced users or in consultation with ABIOMED. Although the motor speed can vary from 3,000 to 10,000 rpm, it should be kept within narrower bounds, which vary depending on the beat rate.

Reasons for changing the motor control speed limits include:

- Understroking (increase the maximum motor speed)
- Overstroking (decrease the minimum motor speed)

The minimum and maximum motor speeds are set in the Stroke Control Limits popup in the AbioCor Setup menu. Contact ABIOMED for assistance before changing the motor speed limits.

7 Caring for a Patient with an Implanted AbioCor System

Contents

IMPORTANT NOTICE: Patient management information given in this section is intended to provide suggested guidelines. Each clinician must determine the suitability of these guidelines based on the needs of the individual patient. These guidelines are not intended to be a substitute for the independent medical judgment of the clinician.

The AbioCor Patient

The key characteristic of an AbioCor patient is that their natural heart has failed and been replaced with an AbioCor system. Before implantation of the AbioCor system, the patient:

- Experienced biventricular failure
- Was not a transplant candidate
- Failed to respond to maximal medical therapy

Replacement of the failing biological heart with an AbioCor System should reestablish a cardiac index above 2.5 $L/m/m^2$. With this cardiac index, recovery of end organs that are dysfunctional due to the patient's heart failure should occur within 2 to 3 weeks.

Special characteristics of patients with an implanted AbioCor System

The post-operative AbioCor patient will be in a condition similar to that of a patient after VAD implant or a heart transplant. The differences between VAD implants and the AbioCor are discussed in the sidebar.

Differences between the AbioCor System and VAD systems

There are a few noteworthy differences between the AbioCor System and VAD systems:

- The AbioCor System completely replaces the ventricles, while VAD systems supplement the ventricle.
- There is no hand pump with the AbioCor System. There is no way to manually support the AbioCor patient with a hand or foot pump.
- Unlike typical VAD systems, the AbioCor has no percutaneous connections.
- Unlike typical VAD systems, the AbioCor is actively filled. This means that medical conditions such as hypovolemia can affect the AbioCor, causing inflow limiting and decreased cardiac output, or other problems.

Care and monitoring of the patient after implantation of an AbioCor System is similar in many respects to the care and monitoring for patients after ventricular assist device (VAD) implantation or a heart transplant. However, because the AbioCor completely replaces the patient's natural heart, there are significant differences in care. Typical cardiac and VAD patients are managed medically, while some conditions that occur in patients implanted with the AbioCor System need to be managed by manipulating the AbioCor operating parameters.

Patients with an AbioCor System have no ECG

- The AbioCor has no cardiac conduction system
- No ECG monitoring or leads are necessary
- Anti-arrhythmic medications should not be used
- No pacemaker is necessary

The design of the AbioCor System also causes other differences in patient care. Table 7.1 summarizes the similarities and differences between management of AbioCor patients and other cardiac patients.

Table 7.1 Summary of Similarities and Differences between AbioCor and Other Cardiac Patients

Similarities
• Patient Monitoring
• Volume Management
• Pressure Management
• Hemostasis Management
• Respiratory Management
Differences
• AbioCor device management replaces cardiac conduction system management.
— No ECG
— No pacemaker
— No antiarrhythmics or inotropes
• CPR and MRI can be extremely hazardous to an AbioCor patient

There are small but significant differences between AbioCor and other cardiac patients even in the aspects of care that are generally similar. The following sections discuss these differences.

Overview of Patient Management

The intent of post-operative management is to return the patient to normal hemodynamics and, ultimately, to return the patient to the home environment with good quality of life. Critical sub-goals involved in this task include:

- extubating
- removing chest tubes, Foley catheters and monitoring lines
- pain control
- recovery of end organ function
- provision of adequate nutrition
- mobilization as soon as possible

The following sections present an overview of the key aspects of management of a patient with an AbioCor System, focusing on the aspects of management that differ from management of VAD or heart transplant patients. These key aspects are:

- The absence of a cardiac conduction system
- Patient monitoring
- Volume/fluid management
- Pressure management
- Hemostasis management
- Respiratory and ventilator management
- Other considerations

No Cardiac Conduction System

The AbioCor has no cardiac conduction system. Monitoring and treatments for the cardiac conduction system and other biological heart functions are not necessary. This causes several differences in treatment:

- ECG monitoring and leads are not necessary
- No pacemaker or pacemaker leads

- Cardiac medications will have generally different effects based on their activity outside the heart
- Antiarrhythmics will have no effect
- Inotropes will have no effect
- Monitoring of cardiac enzyme levels is not needed

Patient monitoring

Patient monitoring for AbioCor patients is similar to monitoring for VAD or heart transplant patients, except that AbioCor parameters should be monitored, and cardiac enzyme monitoring is not necessary.

A stethoscope will hear the sounds of the AbioCor system rather than the normal heart beat. Sound from the AbioCor System may obscure normal lung and abdominal noises.

Continuous Post-Implant Monitoring

The parameters listed in Table 7.2 should be monitored in the immediate post-operative period.

Table 7.2 Parameters to be Monitored Continuously

AbioCor Parameters	• Left and right hydraulic pressures • Beat rate • Balance • Left and right motor speeds • AbioCor estimated cardiac output (liters/minute)
Other Parameters	• Arterial blood pressure (ABP) • Central venous pressure (CVP) • Left atrial pressure (LAP) • Pulse oximetry

The ABP, CVP and AbioCor output should correlate with each other, and will help diagnose problems as they arise.

Daily Post-Implant Monitoring

In addition to these continuously monitored parameters, care for a patient implanted with an AbioCor System should include:

- Daily physical examination around the implanted TET to check for evidence of swelling or fluid accumulation, as discussed in Section 6.

- Daily testing of a variety of other parameters, as listed in Table 7.3. This tracking will aid in monitoring recovery of the patient's end organ function.

Table 7.3 Parameters to be Monitored Daily

Parameter Group	Parameter
Renal	• Creatinine • BUN • Electrolytes • Creatinine clearance • Urine appearance/analysis
Liver	• Total bilirubin • SGOT • SGPT • Alkaline phosphatase • Jaundice
Lung	• Respiratory rate • Positive end expiratory pressure • $Fi0_2$ • Blood gases • Pulmonary function tests • Chest x-rays
Hematology	• Hematocrit • Hemoglobin • Platelet count • Retic count • Fibrinogen • LDH • Plasma free hemoglobin • Platelet aggregation • Bleeding time • PT • PTT • INR • Thrombelastogram • Fibrin split products • Active bleeding

Table 7.3 Parameters to be Monitored Daily (Continued)

Nutritional	• Caloric count • Albumin • Total protein • Prealbumin • Positive nitrogen balance
Neurological	• NIH stroke scale
Physical Activity	• In chair • Standing • Walking • Range of motion • Rehabilitation • Pain symptoms
Psych/Social	• Compliance • Depression • Activities • Family/visitors • Returning to routine • Regaining control
Quality of Life	• Chart activities of daily living

Volume/fluid management

The patient's fluid volumes can affect the operation of the AbioCor System, especially hypovolemia, which can cause inflow limiting. Volume management should include fluid intake and output measurements.

Fluid and volume management also includes assessment of the AbioCor left and right hydraulic waveforms to evaluate the possibility of hypovolemia.

Hypovolemia and Inflow Limiting

On the AbioCor System, hypovolemia manifests as right side inflow limiting or simultaneous inflow limiting on both the left and right sides, along with the resulting decrease in cardiac output. The filling pressures for each side, LAP and RAP (CVP), also decrease.

Hypovolemia can be caused by:

- Diuretic therapy
- Hemorrhage

- "Third space" fluid losses

When clinically prudent, inflow limiting due to hypovolemia should be treated by giving additional fluid volume, using blood products and albumin rather than crystalloid. If the patient cannot tolerate additional fluid volume, inflow limiting can be managed by changing the AbioCor operating parameters, as discussed in Section 6.

Pressure management

Blood pressure management should aim to maintain pressures within standard physiologic ranges, as shown in Table 7.4. These pressure ranges are the same as those expected for individuals with normal hearts.

Table 7.4 Suggested Blood Pressure Target Ranges for AbioCor Patients

Pressure Measurement	Target Range (mm Hg)	Notes
MAP	80 – 100	
CVP	10 – 15	Exceeding this range may cause respiratory problems including pulmonary congestion or edema.
LAP	10 – 15	Exceeding this range may cause liver dysfunction.

The tools available to manage blood pressure include blood pressure medications, fluid volume management, and AbioCor parameter settings. The effects of AbioCor parameters were discussed in Section 6 and are summarized in Table 7.5. Table 7.6 lists the medications most commonly used for blood pressure management with AbioCor patients.

Table 7.5 Effects of AbioCor Settings on Blood Pressure

Setting	Effect on blood pressure
Beat rate	Increasing the beat rate decreases CVP.
Balance Control	Increasing the balance control setting increases LAP.
Motor Speed	Under automatic control, motor speed increases as afterload pressures increase.

Table 7.6 Medications Commonly Used to Control Blood Pressure in AbioCor Patients

Vasoconstrictors (used to maintain SVR)
Vasopressin (widely used for AbioCor patients)
Levophed®
Neo-synephrine
Vasodilators (used to maintain SVR and PVR)
Nipride®
Nitric oxide
Primacor®
Isuprel®

Hemostasis management

Hemostasis management seeks to achieve and maintain normal hemostasis in the AbioCor patient to allow clot formation without producing inappropriate thrombosis. This requires balancing the clot-producing coagulation and platelet systems and the clot-dissolving fibrinolytic system.

Hemostasis should be monitored by thrombelastography (TEG), a technique that tests whole blood coagulation by measuring the viscosity of a blood sample over time, as it clots. The targets for anticoagulation management are shown in Table 7.7.

Table 7.7 Suggested Anticoagulant Targets for AbioCor Patients (after hemostasis 2.0 times baseline)

Target Variable	Range
ACT (activated coagulation time)	180 – 200 sec
PTT (partial thromboplastin time)	50 – 70 sec
INR (International normalized ratio)	2.5 - 3.5

Although the AbioCor System is designed to minimize clot formation, implantation of the AbioCor System is likely to shift the balance toward clot formation and increase the likelihood of thrombosis. Anticoagulant medications are used to shift the balance back. Table 7.8 lists the anticoagulant medications commonly used in hemostasis management for AbioCor patients.

Table 7.8 Medications Commonly Used for Hemostasis Management of AbioCor Patients

Medication	Notes
Anticoagulants	
Heparin	Used for initial, short duration therapy
Coumadin	Longer term anticoagulant therapy
Platelet System	
Dipyridamole (Persantine®)	Platelet stabilization
Aspirin	Inhibits platelet aggregation
Ticlopidine (Ticlid®) or Clopidogrel (Plavix®)	Used for patients who can't tolerate aspirin
Fibrinolytic System	
Aminocaproic acid (Amicar®)	Inhibits fibrinolysis
Aprotinin (Trasylol®)	Attenuates inflammation, fibrinolysis, and thrombin generation

Respiratory and ventilator management

Ongoing assessment of an AbioCor patient's pulmonary status is necessary to ensure adequate oxygenation. Some patients may require an aggressive pulmonary toilet or frequent bronchoscopy.

Continuous monitoring of SVO_2 and frequent monitoring of arterial blood gases is recommended. A decrease in SVO_2 commonly results from hypoperfusion. The patient may need blood if an SVO_2 decrease is accompanied by low filling pressures or low hemoglobin levels.

Like any post cardiac surgical patient or patient on VAD support, the patient implanted with the AbioCor System should be moved off ventilator support as soon as clinically prudent. Long-term ventilator support, until the patient recovers sufficient strength to breathe independently, may be required for debilitated patients. To prevent aspiration of food, swallowing should be assessed post-extubation and before the patient is advanced to an oral diet.

The high intra-thoracic pressures associated with positive end expiratory pressure ventilation (PEEP) may cause transient inflow limiting. Inflow limiting due to high PEEP can be managed by decreasing the tidal volume while increasing the rate to maintain a constant level of oxygenation. If PEEP levels greater than 7 cm H_2O are required, decreasing the patient tidal volume should be considered, and the patient's ability to tolerate high PEEP levels should be evaluated frequently.

Other considerations

Inappropriate Postures

Patients implanted with an AbioCor System should avoid deep forward bends. These may cause discomfort or pain from the rigid AbioCor components, and could affect blood flow causing inflow limiting, low blood pressure, and fainting.

X-Ray Shielding

As discussed in Section 2, metal objects should be kept away from the TET. This includes the lead aprons used when taking X-rays.

To avoid heating of the TET coil and possible thermal injury when a shielding apron is being used, place a Styrofoam® block or a folded towel at least 3 inches thick between the External TET coil and the shielding apron to prevent induction heating.

No CPR

CPR will not assist the patient, and may cause internal injury and life-threatening bleeding

No MRI

MRI may irreparably damage the AbioCor internal components.

No Cardiac Catheters

Cardiac catheters may damage the blood contacting surfaces in the Thoracic Unit and promote thrombus buildup. Do not use a Swan-Ganz catheter or other catheters to measure blood pressure within the Thoracic Unit.

Moving the patient

Patients with an implanted AbioCor System can be moved using procedures similar to those for other cardiac patients. The patient is moved in a wheelchair, and the Console is moved on a separate cart. A backup external power source for the AbioCor System must be available at all times during transport. Two backup power source are available: an AbioCor Console with an External TET and RF Communications Module, or the Patient-Carried Electronics (PCE) with an External TET.
PCE use is summarized in Appendix A, and is detailed in a separate PCE Manual.

Console Battery Charge

A fully charged Console battery has approximately 40 minutes of operation

Transporting an AbioCor patient using the AbioCor Console

Preparation

- Install portable oxygen canisters on the wheelchair if needed.
- Ensure that a backup Console is available, and that it has been set up correctly to communicate with the patient's Implanted controller as described in Appendix C.
- Have an extension cord available to make it more convenient to plug the Console into the wall.
- Remove any connections to patient monitoring equipment from the Console.
- Check both the primary and backup Console battery voltages. They should both be greater than 34V.

Transport

- When ready to move, unplug the Console from the wall. The Console will display the alarm "Power Failure – AC Mains" until the device is plugged back into the wall.
- While moving, the wheelchair driver and Console operator should ensure that the RF and TET wires are never strained unnecessarily. The Console operator should constantly monitor the Console battery level.
- Plug the Console into wall AC when practical to minimize battery use.

- If the battery becomes low, a white (advisory) alarm will occur. This will be followed by a yellow (serious) alarm as the battery voltage drops.

Arrival

Plug the Console into wall AC immediately upon arriving at the patient's destination. Ensure that the Console is getting power from the wall AC, and that the Console power alarms are cleared.

Bathing the patient

Bathing and wound care for AbioCor patients is similar to that for other cardiac patients. The patient can be bathed while in bed until he or she has regained sufficient strength and mobility to allow independent showering. If the Implanted Battery is fully charged, the TET can be removed for short periods (less than 20 minutes) for wound inspection, dressing changes, and bathing.

The patient can bathe or shower once he or she has recovered sufficiently. During bathing and showering, the PCE TET should be worn to maintain power to the AbioCor System and to allow alarm monitoring.

Excursions out of the hospital

Out-of-hospital excursions, typically to a local park or restaurant, assess the patient's ability to function outside the hospital, and serve as a critical part of preparation for discharge.

Before undertaking an out-of-hospital excursion, the patient must:

- Not need ventilator support
- Not need infusions
- Be able to walk for 100 ft without assistance

The excursions typically last no more than 2 hours. The patient travels in a van equipped with AC power, and is accompanied by his doctor, a nurse, a driver, and a caregiver. It is prudent to test the van and the excursion route before the excursion.

8 Transitioning the AbioCor Patient to Home Living

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Overview

Discharge from the hospital and a return to living in the home environment is the ultimate goal for a patient who has received an AbioCor System. The transition to home living involves careful preparation and assessment of the patient, the patient's caregivers, and the patient's home environment and support structures. This section contains a summary of discharge planning and preparation.

Discharge planning and preparation involves several areas, each of which is summarized below:

- Patient condition
- AbioCor System configuration
- Home environment setup
- Patient and caregiver training
- Transportation
- Discharge

Patient condition

The patient must be sufficiently healthy to function in the home environment. Some guidelines for assessing this may be:

- In good neurological condition
- Hemodynamically stable
- Free of active infection
- Receiving oral nutrition
- Able to pass a 6-minute walk test or equivalent
- On a stable anticoagulant regimen

AbioCor System configuration

The following AbioCor System components and backups must be available to the patient for home use:

- Two Consoles and two eleven-foot TET coils
- Two radio frequency transceivers
- Two PCE Control Modules and two five-foot TET coils
- Eight pairs of PCE batteries
- Two external battery chargers
- Two AC/DC adapters for the PCE drivers
- Two sets of harnesses for the PCE
- A six-month supply of DuoDerm for the TET
- An uninterruptible power supply (UPS) with a minimum of 4 hours of capacity

Home environment setup

The home electrical system must be able to support the AbioCor System. The operation of an AbioCor System in the patient's home should be tested before discharge.

Caregivers must be available to be with the patient at all times.

The local EMS Provider should be familiarized in the care of the AbioCor patient.

Patient and caregiver training

The patient and all caregivers must be trained in caring for the patient and in operation of the AbioCor System. This training must include information on several topics related to the use of the AbioCor System.

Table 8.1 summarizes key topics on which patients and caregivers should be trained.

Table 8.1 Training Topics for Patients and Caregivers

Topics
Alarm handling: • Inflow limiting • Low flows • TET misalignment • RF communication
Using the Home Mode and navigating the Home Screen
TET management
Console use
PCE use
Function of the AbioCor System components
Living with the AbioCor • Bathing • Sleep • Exercise • Excursions
Medical and nutritional needs
Safety rules and emergency response
Who to contact if you have an emergency or need assistance

Transportation

There are no special ground transportation needs. Whenever they travel, patients should bring enough battery power to last twice the intended duration of the trip. Patients may also want to install an inverter in their vehicle to provide AC power.

Plans should be made for emergency transport in case it is needed.

Discharge

Discharge occurs in four stages:

1. Short out-of-hospital trips to a local park or restaurant, accompanied by family and professional caregivers.

2. Day trips to a local facility that simulates the home environment, also accompanied by family and professional caregivers. During these trips, family caregivers should take on more and more responsibility for caring for the patient and managing the AbioCor System.

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3. Overnight stays at a local facility that simulates the home environment, probably the same as in stage 2, accompanied only by a family caregiver. Professional caregivers should be available for telephone support and emergency response.

4. Discharge to home. Before discharge, the medical team will evaluate the patient's readiness for discharge.

9 Alarms

Contents

Overview

The AbioCor System monitors various functions to determine whether specific operational parameters are within expected limits. When a parameter goes outside its specified limits, the AbioCor Console sounds an alarm tone and displays an alarm message. The alarm tone indicates the severity of the alarm. The alarm message is color-coded for severity and provides details on the cause of the alarm.

The AbioCor Console Alarms User's Guide is a quick reference guide to the AbioCor alarms.

Alarms are divided into three levels:

- Advisory (white)
- Serious (yellow)
- Life-threatening (red)

To speed the process of determining alarm details, each level is annunciated using a particular set of audible and visual indicators, listed in Table 9.1.

Table 9.1 Alarm Levels

Severity level	Description	Audible indicator	Visual indicator
Advisory	Non-life-threatening	eeee-oo Sounds once. Relatively quiet.	Flashing alarm message on a white background
Serious (General)	May become life-threatening if not addressed immediately	ee-ee-ee-... Repeats four times per second until silenced or resolved.	Flashing alarm message on a yellow background
Serious (TET misalignment)	TET should be realigned. This alarm has a unique sound.	oooooooo-ee-__... Repeats indefinitely until silenced or resolved.	Flashing alarm message on a yellow background
Life-threatening	Immediately harmful or life-threatening	eeee-oooo-eeee-oooo... Repeats indefinitely until silenced or resolved.	Flashing alarm message on a red background

Note: In the audible indicator descriptions, "eeee" indicates a high-pitched beep, "oooo" indicates a low pitched "boop", and "____" indicates a quiet period. Each letter represents one eighth of a second.

Clinical Mode Alarm Displays and Controls

In Clinical Mode, the Console displays alarm indicators to the right of the waveform area (see Figure 9.1).

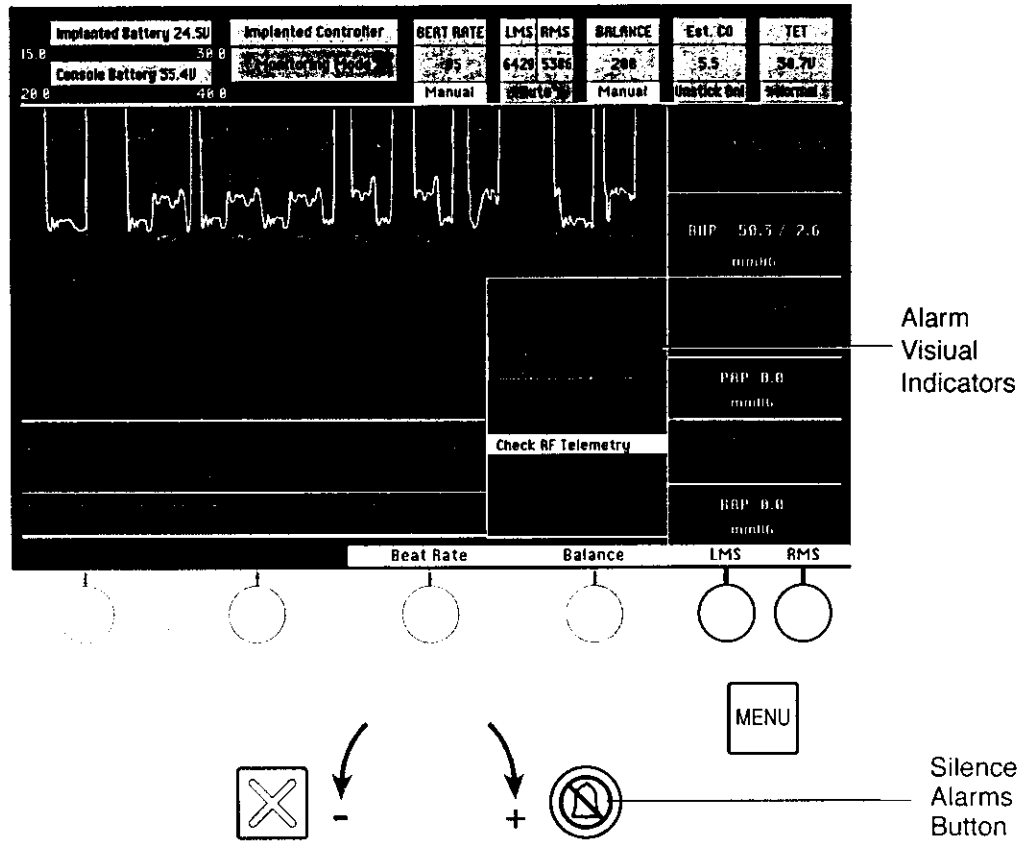


Figure 9.1 Alarm Indicators and the Silence Alarms Button

Press the Silence Alarm button to silence an alarm for two minutes.

Alarm Operating Modes

***WARNING:** Only an authorized user is permitted to change Console alarm properties.*

The AbioCor Console has three modes of alarm operation:

- Standard
- Disabled
- Log Only

These alarm modes are described in detail below. Authorized users can select the alarm handling method for each individual alarm in the Alarm Configuration Menu, found in the AbioCor setup menu. Only advanced users and ABIOMED personnel should be authorized to change alarm properties.

Standard alarm operation

In standard operation, pressing the Alarm Silence button turns off the alarm sound for two minutes, or until a new alarm occurs.

- Pressing the Silence/Clear Alarms Button (see Figure 9.1) on the keypad silences the audible indicator for *two minutes*. The associated visual indicator stops flashing.
- If the alarm condition persists longer than two minutes, the audible indicator sounds again, and the visual indicator resumes flashing.
- The audible alarm sounds immediately if alarm occurs for any *other* parameter of the same (or higher) severity level.

Disabled alarms

A disabled alarm will not trigger an alarm sound or message. Disabled alarms will remain completely inoperative (audible and visible indicators) until they are re-enabled.

Alarms That Resolve on Their Own

The audible indicator will shut off if an alarm condition is resolved (changes to a within-limits condition) before the Alarm Silence Button is pressed. The visual alarm message, however, is displayed until the user presses the Alarm Silence Button. This allows the user to determine the identity of the alarm that occurred.

Alarm message summary

Table 9.2 lists and briefly describes all the alarm messages that can appear on the AbioCor Console.

Table 9.2 AbioCor Console Alarm Messages

Placeholder for Alarm Table			
Alarm Message Details			

Appendix A: Patient-Carried Electronics

This Appendix summarizes the operation of the Patient-Carried Electronics (PCE) and is intended as a quick reference for clinicians. A separate PCE manual provides more detailed information.

Appendix B: Overview of Home Mode

This Appendix summarizes the operation of the AbioCor Console in Home Mode, and is intended as a quick reference for clinicians that usually operate in Clinical Mode. A separate Patient Manual provides a more detailed description of Home Screen operation.

The Home Screen shows an alarm area, four control panels that can be opened or closed, and a menu. Figure B.1.a and B.1.b show the home screen with all the control panels open and closed, respectively.

The alarm area displays the three highest-priority active alarms, color coded by severity. See Section 9 for information on the AbioCor alarms.

A user can show or hide any of the four control panels by pressing the Open/Close button for the desired panel. The four control panels are also shown automatically when a relevant alarm occurs.

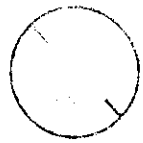
If RF signal quality is poor, the control panels will have a speckled gray background to represent static.

Soft Button Operation in Home Mode

RF Panel	Pressing this button opens or closes the RF Panel, which shows the quality of the RF (radio frequency) signal from the patient to the Console and from the Console to the patient. The color of the arcs indicates the signal quality. See Section 6 for information on handling RF Communications problems.
Power Panel	Pressing this button opens or closes the Power Panel, which shows: • The active power source for the AbioCor System • The status of TET power transmission • The battery charge levels See Section 6 for information on the AbioCor power system.

Heart Rate (Beat Rate) Range

The range of beat rate settings allowed can be limited using the Input Beat Range popup in Clinical Mode, as described in Appendix G. The scale in the heart rate panel shrinks to the allowed beat rate settings.

Heart Rate (Beat Rate) Panel 	Pressing this button opens or closes the Heart Rate Panel, which displays and controls the current heart rate. The icon at the top of the panel shows the current estimated cardiac output. The current heart rate is shown in a black oval on the heart rate range scale. The heart rate setpoint is shown in a blue arrow to the right of the heart rate scale, if it is different from the actual heart rate. Note that the Heart Rate is referred to as the Beat Rate in Clinical Mode. See Section 6 for more information on setting the Beat Rate.
Left Heart Pressure (Balance) Panel	Pressing this button opens or closes the Left Heart Pressure Panel, which displays and controls the balance setting. It operates like the Heart Rate Panel. Note that Left Heart Pressure is referred to as Balance in Clinical Mode. See Section 6 for more information on setting the Balance.
PCE Alarm Test	Pressing this button trips the PCE Alarm to test it when switching to the PCE. See the Appendix A or the PCE manual for more information on testing the PCE Alarm.
Deactivate Console 	Pressing this button deactivates the Console after a confirmation message. See Section 5 for more information on deactivating the Console.

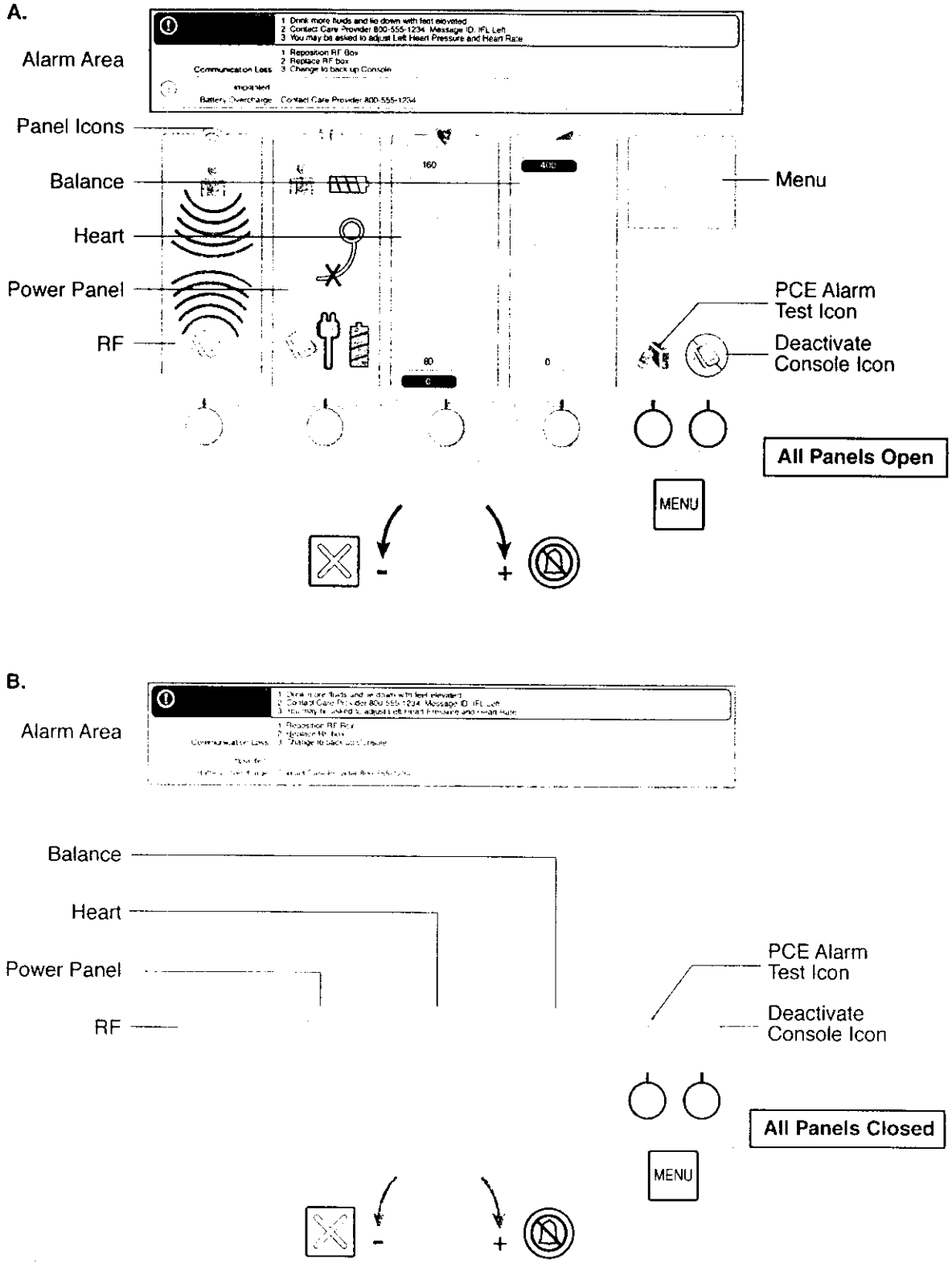


Figure B.1 AbioCor Console Home Screen and Keypad A) All panels and the menu open B) Panels and menu closed

Appendix C: Installing and Setting Up a Console for a New Patient

Several configuration steps are necessary to set up a Console for use with a new patient. The following parameters must be configured:

- transmitter ID
- patient ID
- TCP/IP address
- RF/TET channel mode
- TET Alignment alarm delay

Transmitter ID

Consoles must be configured to communicate with specific Implanted controllers by reading the Implanted controller ID from the Controller. It may be necessary to perform the procedure in the hospital if, for example, a Console is moved from one patient to another.

This procedure describes the steps needed to set up a new Console for a patient with the AbioCor System.

1. Connect the new Console to AC power and power it up. See Section 4 for more information on steps 1-3.
2. Disconnect the existing External TET from the old Console and connect it to the new Console.
3. Disconnect the existing RF Communications Module from the old Console and connect it to the new Console.
4. If needed, go to the Clinical Mode. See Section 4.
5. Read the ID number of the Implanted Controller following the procedure in Table C.1.

Table C.1 How To Read the Implanted Controller ID Number

Your Action	AbioCor Console Response
1. Go to Main Menu\AbioCor Setup... \Select Controller See Section 5 for detailed instructions.	The Controller Source window appears.
2. Verify that RF Comm is showing in the Controller Source area. If it isn't, use the selector knob to move to the Controller Source display and change the controller source to RF Comm.	
3. Use the Selector Knob to move to the Select Transmitter ID area: • If you know the patient's Transmitter ID, use the manual ID Entry control. • If you do not know the patient's ID, use the Select ID from list control and select the top entry.	The console reads the Implanted Controller ID number from the Implanted Controller. The new ID number is displayed in the Controller ID area. If the ID number is not displayed, connect the TET and RF module to the original console and contact ABIOMED for assistance.
4. Use the Selector Knob to move to the Accept box and press the knob	The Controller Source popup disappears, showing the main screen.
5. Verify that the main screen displays LHP and RHP waveforms from the patient's Implanted Controller.	If the new waveforms are not displayed, connect the TET and RF module to the original console and contact ABIOMED for assistance.

Patient ID

Each patient is assigned a unique ID number that is used to label files generated by the AbioCor System. These files are used to monitor the AbioCor System during implantation and to diagnose system concerns. The Patient ID must be set on each console assigned to the patient.

To set the Patient ID, follow the procedure described in Table C.2.

Table C.2 How to Set the Patient ID

Your Action	AbioCor Console Response
1. Go to Main Menu\Console Setup\Patient ID.	The Patient ID popup appears.
2. Use the calculator to edit the Patient ID number.	
3. Turn the Selector Knob to scroll to the "Accept" button and press the Selector Knob.	
4. Press the Selector Knob again to accept the new Patient ID.	

TCP/IP Setup

The TCP/IP Setup menu is used to configure the AbioCor Console to allow remote viewing of real-time AbioCor data. This menu is also used to download other diagnostic information.

The information for this setup can be obtained from the TCP/IP setup table on the old Console and transferred to the new Console.

To transfer the information, follow the procedure described in Table C.3.

Table C.3 How to Set Up for Remote Monitoring and Data Downloading

Your Action	AbioCor Console Response
1. On the old Console, go to Main Menu\Console Setup...\TCP/IP Setup.	The TCP/IP setup menu appears.
2. Record the following information: • Incoming TCP/IP Address • Outgoing TCP/IP Address • Network Submask • Default Gateway • FTP User ID • FTP Password • Remote Password	
3. On the new Console, go to Main Menu\Console Setup...\TCP/IP Setup. Enter the recorded information in the appropriate boxes. (If this is a new installation, work with your hospital information systems department and ABIOMED to set up this feature for your facility.)	
4. Select "Save" and then select "Exit".	

RF/TET Channel Mode

Consoles for patients who are discharged (or about to be discharged) are generally set up in TET Channel Mode.

To change the Console from RF Mode to TET Channel Mode, follow the procedure described in Table C.4.

Table C.4 How to Change from RF Mode to TET Channel Mode

Your Action	AbioCor Console Response
1. Go to Main Menu\Console Setup\RF/TET Channel mode selection.	The RF/TET Channel mode selection box appears.
2. Select "TET Channel Mode". (See Section 6 for information about modes.)	

Appendix D: Console Back Panel Interface Specifications

Item	Electrical Interface
Patient Monitor: Analog/Physiological Inputs	Connector: 8-pin, D-sub, coaxial (DB-37 shell) Min/max input voltage: –5 to +5 V Pin 1: Aortic Pressure; Pin 2: Pulmonary Artery Pressure Pin 3: Left Atrial Pressure; Pin 4: Right Atrial Pressure
Remote Alarm Annunciation (Switch Closure)	Connector: standard ¼" 2-pole phone jack Max input voltage: 125 VAC/60 VDC Max switch current: 1 amp Contacts: normally open (open – no alarm; closed – Console audible alarm activated) Contact resistance: < 1 Ω
TCP/IP Output Port (data export)	Connector: standard DB-9 female with ABIOMED adapter (P/N 0034-4662) Data format: 10baseT
Remote Video Out	Connector: standard high-density DB-15 female Video standard: SVGA

Appendix E: Data Capture

The Data Capture function saves a 4-minute long snapshot of all the data collected by the AbioCor System. The snapshot begins two minutes before Data Capture was started and ends two minutes afterward. The snapshot can be retrieved by an ABIOMED engineer or by remote data communications.

Typically, Data Capture is used to record unusual events for later review and analysis.

How to Start Data Capture

Your Action	AbioCor Console Response
1. Press the Menu button	Menu appears
2. Turn the Menu Selector Knob to select "Start Data Capture!"	"Start Data Capture" is highlighted
3. Press the Menu Selector Knob	Data capture begins.
4. Data capture ends automatically	
5. Contact ABIOMED to retrieve the captured data for review and analysis.	

Appendix F: System Specifications

Table F.1 Thoracic Unit Performance Specifications

Attribute	Specification
Flow, from a mean left filling pressure of 10 mm Hg into a mean systemic arterial pressure of 100 mm Hg and from a mean right filling pressure of 10 mm Hg into a mean pulmonary pressure of 25 mm Hg.	4 to 8 liters per minute
Displacement Volume, Left Blood Pump	30 to 60 cc
Displacement Volume, Right Blood Pump	30 to 60 cc
Volume, Balance Chamber	10 cc
Speed, Pump Motor	3000 to 10,000 rpm
Range, Hydraulic Pressure Transducers	383 to 1175 mm Hg absolute
Repeatability, Hydraulic Pressure Transducers (full range)	± 5 mm Hg
Repeatability, Hydraulic Pressure Transducers (in range 750 to 790 mm Hg absolute)	± 2 mm Hg
Physical Attributes Height Width Weight	 126 mm (5.0 inches) maximum 99 mm (3.9 inches) maximum 1090 grams (2.4 lbs.)
Materials Energy Converter, Exterior Metal Exterior Blood Pump Area Interior of Blood Pumps, blood contacting membranes Cable Outer Insulation Cable Connector Cuffs Grafts Quick Connectors	Titanium Epoxy Angioflex (polyetherurethane) Carbothane® (an implantable grade of polyurethane) Titanium Velour Dacron® Titanium

Table F.2 Thoracic Unit Environmental Specifications

Attribute	Specification
Temperature, Operating	10°C to 40°C
Temperature, Storage	10°C to 40°C
Humidity, Relative	0 to 100% condensing
Pressure, Atmospheric	661 to 791 mm Hg

Table F.3 Implantable Controller Performance Specifications

Attribute	Specification
Physical Attributes Height Width Thickness Weight Enclosure and lid (exterior surface) materials	 114 mm (4.5 inches) 71 mm (2.8 inches) 33 mm (1.3 inches) 261 grams (0.57 lbs.) Titanium
Frequency, RF Operation	916.5 MHz
Power, RF Transmitter	1 milliwatt
Operating Voltage	17.0 to 45.0 VDC

Table F.4 Implantable Controller Environmental Specifications

Attribute	Specification
Temperature, Operating	20°C to 40°C
Temperature, Storage	-40°C to 40°C
Humidity, Relative	0 to 100% condensing
Pressure, Atmospheric	500 to 825 mm Hg

Table F.5 Implantable Battery Performance Specifications

Attribute	Specification
Battery coulombic capacity, when discharged with an 800 mA current at 37°C, from fully charged to fully discharged, (at beginning of life)	0.55 amp-hours
Battery Voltage	17.0 to 24.2 VDC
Battery Operation Time, (at beginning of life)	30 minutes minimum
Minimum cycle life, number of battery discharge cycles from fully charged to fully discharged, at blood flow rate of 6 L/min, before battery capacity decreases to 50% of its initial capacity	> 230 cycles
Maximum charging voltage	45.0 VDC
Minimum voltage for battery charging	28.0 VDC
Physical Attributes: Height Width Thickness Weight Enclosure and lid (exterior surface) materials	 44 mm 104 mm 99 mm 590 grams Titanium

Table F.6 Implantable Battery Environmental Specifications

Attribute	Specification
Temperature, Operating	20°C to 40°C
Temperature, Storage	-40°C to 40°C
Humidity, Relative	0 to 100% condensing
Pressure, Atmospheric	500 to 825 mm Hg

Table F.7 Implantable TET Performance Specifications

Attribute	Specification
TET Output Voltage for Autoregulation (constant load of 35 ohms)	30 ± 2 VDC
Spatial envelope, center of front side of Implantable TET referenced to center of patient side of External TET	Half sphere, with radius of 25.4 mm (1.0 inch)
Physical Attributes Diameter (not including velour material) Height Cable Length Weight	 76 mm (3.0 inches) 13 mm (0.5 inches) 180 mm (7.0 inches) 174 grams (0.38 lbs.)
External Surface Materials TET Connector Cable and Connector Over-molding	 Angioflex and Velour Titanium Carbothane (an implantable grade of polyurethane)

Table F.8 Implantable TET Environmental Specifications

Attribute	Specification
Temperature, Operating	20°C to 40°C
Temperature, Storage	-40°C to 40°C
Humidity, Relative	0 to 100% condensing
Pressure, Atmospheric	500 to 825 mm Hg

Table F.9 Implantable Cable Performance Specifications

Attribute	Specification
Length, Implantable TET cable section	178 mm (7.0 inches)
Length, Implantable TU cable section	178 mm (7.0 inches)
Length, Implantable Battery cable section	254 mm (10.0 inches)
Length, Antenna	178 mm (7.0 Inches)
Diameter, largest diameter on any single cable section	22 mm (0.8 inches)
Weight	130 grams (0.29 lbs)
External Surface Materials Connector Cable Outer Insulation, and Connector Over-molding	 Titanium Carbothane (implantable grade of polyurethane)

Table F.10 Implantable Cable Environmental Specifications

Attribute	Specification
Temperature, Operating	20°C to 40°C
Temperature, Storage	-40°C to 40°C
Humidity, Relative	0 to 100% condensing
Pressure, Atmospheric	500 to 825 mm Hg

Table F.11 AbioCor Console Performance Specifications

Attribute	Specification
Battery Operation Time, at beginning of life, with blood flow rate of 6 L/min and power supplied by the TET system	50 minutes minimum
Battery Operation Time, at beginning of life, with blood flow rate of 8 L/min and power supplied by the TET system	40 minutes minimum
Power Consumption, System	175 watts
Capacity, Flash Memory Card	128 megabytes
Front Panel Angle, mechanical, from horizontal (with fold-out leg extended)	32°
Viewing Angle, optical, horizontally off-axis from perpendicular to Graphical Display	50° minimum
Viewing angle, optical, vertically off-axis from perpendicular to Graphical Display	35° minimum
Separation, Maximum, Console RF Communications Module from Implantable Controller	30 cm (1.0 foot)
Frequency, RF Operation	916.5 MHz
Power, RF Transmitter	1 milliwatt
Physical Attributes Width, overall (including antennae in folded position) Depth, with fold-out leg retracted Depth, with fold-out leg extended Height, with fold-out leg retracted Height, with fold-out leg extended Weight	 41.9 cm (16.5 inches) 47.0 cm (18.5 inches) 52.1 cm (20.5 inches) 14.0 cm (5.5 inches) 26.7 cm (10.5 inches) 28 pounds

Table F.12 AbioCor Console Environmental Specifications

Attribute	Specification
Temperature, Operating	10°C to 40°C
Temperature, Storage	-40°C to 65°C
Operating Humidity, Relative	30% to 75%
Storage Humidity, Relative	10% to 90%
Pressure, Atmospheric	500 to 825 mm Hg

Table F.13 External TET Performance Specifications

Attribute	Specification
TET Power, Deliverable	150 watts maximum
TET RF Frequency	320 ± 5 kHz
Materials, External Surface (Cable and coil covering)	Silicone
Diameter, External TET coil	133 mm (5.25 inches)
Thickness, External TET coil	13 mm (0.5 inches)
Length, Cable	3.0 m (10 feet)
Weight	0.45 kg (1.0 lb.)

Table F.14 External TET Environmental Specifications

Attribute	Specification
Temperature, Operating	20°C to 40°C
Temperature, Storage	-40°C to 40°C
Humidity, Relative	0 to 100% condensing
Pressure, Atmospheric	500 to 825 mm Hg

Appendix G: How-To's for Common Tasks

Contents

How to Set the Beat Rate	
Actions	
Your Action	**AbioCor Console Response**
1. Press the Menu button	Main Menu appears
2. Turn the Menu Selector Knob to select "Show Control Buttons!"	Show Control Buttons! is highlighted
3. Press the Menu Selector Knob	Control Button labels appear
4. Press the Beat Rate soft button.	The Beat Rate control button turns green and displays the current Beat Rate.
5. Turn the Selector Knob to select the desired Beat Rate.	The Beat Rate control button turns yellow and displays new Beat Rate values as you turn the button.
6. Press the Selector Knob.	The Console sends the new setting to the implanted controller. The Beat Rate control button turns green and displays the Beat Rate setting.
7. Confirm the change on the status bar Beat Rate display.	The Beat Rate should change to your new setting within 10 seconds.
8. Continue to monitor the patient's hemodynamics.	

The beat rate can be varied between 85 and 150 beats per minute (bpm). In automatic mode, the AbioCor System adjusts the beat rate to maintain the RAP within a desired range (3 to 25 mm Hg).

Increasing the beat rate tends to:

- increase cardiac output
- decrease the Right Atrial Pressure (RAP) and Central Venous Pressure (CVP)
- decrease filling of the right side of the Thoracic Unit

Decreasing the beat rate has the opposite effects.

Consider the patient's ability to tolerate reduced cardiac output and blood pressure before reducing the beat rate.

See Section 6 for more information.

How to Change to the Home Screen	
Your Action	**AbioCor Console Response**
1. Press the Menu button	Menu appears
2. Turn the Menu Selector Knob to select the View menu	View option is highlighted
3. Press the Menu Selector Knob	View menu appears
4. Turn the Menu Selector Knob to select the Enter Home Screen option	The Enter Home Screen option is highlighted
5. Press the Menu Selector Knob	The Home screen appears

How to Handle RF Communications Problems

Adjust the RF Communication Module alignment by positioning the RF Communications Module directly outside the Implanted Controller.

If necessary, use the Console's Parameter Window for guidance in positioning the RF Communication Module, as follows:

1. Press the Menu button	Main menu appears
2. Turn the Menu Selector Knob to select "Show Param Window!"	Show Param Window! is highlighted
3. Press the Menu Selector Knob	Parameter Window appears
4. Observe the Patient -> Console and Console -> Patient Comm Status areas in the Parameter Window while moving the RF Communications Module	In the Comm Status Area, ">" = good communications "x" = poor communications "0" = no signal
5. Position the RF Communications Module where it gives the best signal.	The Comm Status Area should show an unbroken line of ">" characters.

If repositioning the RF Communication Module doesn't fix the problem, check for other possible causes as follows:

1. Replace the RF Communications Module as follows:

   Unscrew and unplug the connector for the existing RF Communications Module

   Plug in and screw in the connector for the replacement RF Communications Module.

   Position the new RF Communications Module as described above

2. Check for possible sources of electronic interference (e.g., cell phones, two-way radios, or other AbioCor systems) as follows:

   Eliminate devices that may cause electronic interference one-by-one, by turning them off or removing them.

   If communications return to normal when a device is turned off, keep that device turned off or away from the patient.

3. Contact ABIOMED for assistance.

How to Mask an Alarm on the Console

Alarm masking is intended to shut off non-life-threatening alarms for which the alarm sound detracts from the patient's quality of life. A "masked" alarm is de-activated. It will not sound or appear on the console.

Only advanced users should mask alarms.

Your Action	AbioCor Console Response
1. Enter the Alarm Setup menu in the Monitor mode. (Main Menu > Console Setup > Alarms).	The Alarm Configuration menu appears
2. Turn the Selector Knob to select the Alarm group containing the alarm to be masked, and press the Selector Knob.	The Alarm Configuration popup for the selected group appears.
3. Turn the Selector Knob to highlight the alarm to be masked, and press it again.	The background of the selected alarm changes color.
4. Turn the Selector Knob to scroll to the "Alarm" column, and press until the parameter reads "Disabled". **Note:** To unmask the alarm, set the parameter to "Enabled".	The parameter in the Alarm column reads "Disabled".
5. Turn the Selector Knob to scroll back to the Alarm Title and press it.	The background of the selected alarm changes back to the original color.
6. Turn the Selector Knob to scroll to the "Accept" button and press the Selector Knob.	The Alarm Configuration menu appears
7. Confirm that the "Mask" column is checked for the alarm group containing the masked alarm.	
8. Turn the Selector Knob to scroll to "Done" and press it.	The Clinical Mode Main Screen appears.
9. Complete the Alarm De-activation form and have it approved according to hospital and ABIOMED procedures.	

How to Set the Balance	
Actions	
Your Action	**AbioCor Console Response**
1. Press the Menu button	Main Menu appears
2. Turn the Menu Selector Knob to select "Show Control Buttons!"	Show Control Buttons! is highlighted
3. Press the Menu Selector Knob	Control Button labels appear
4. Press the Balance soft button.	The Balance control button turns green and displays the current Balance.
5. Turn the Selector Knob to select the desired Balance.	The Balance control button turns yellow and displays new Balance values as you turn the button.
6. Press the Selector Knob.	The Console sends the new setting to the Implanted controller. The Balance control button turns green and displays the Balance setting.
7. Confirm the change on the status bar Balance display.	The Balance should change to your new setting within 10 seconds.
8. Continue to monitor the patient's hemodynamics.	

The balance setting can be varied between 0 and 400.

Increasing the balance setting tends to increase Left Atrial Pressure (LAP)

Decreasing the balance setting has the opposite effects.

See Section 6 for more information.

How to Manage Inflow Limiting

Inflow limiting occurs when there is not enough blood in an atrium to fill the AbioCor pump chamber.

The AbioCor System will automatically decrease the beat rate or the motor speed on the side opposite the inflow limiting; this tends to reduce the effects of inflow limiting. However, this also tends to decrease the patient's blood pressure and cardiac output. Normal operation will resume when the condition is resolved.

Actions

1. Adjust the patient's posture. The patient should lie down in the Trendelenberg position.
2. Give volume if appropriate.
3. For Left Inflow Limiting, increase the balance setting. (See "How to Set the Balance")

   For Right Inflow Limiting, decrease the beat rate. (See "How to Set the Beat Rate")
4. Other possible causes:

   Inflow limiting with normal or high LAP or RAP may result from tamponade.

   If the patient is on a ventilator, high PEEP may cause inflow limiting. Consider decreasing tidal volume while increasing the rate.

How to Manage Low Flows

Low flow alarms indicate that the Thoracic Unit's cardiac output is too low. It usually results from severe inflow limiting, but may also be caused by problems with the AbioCor System.

The AbioCor System will automatically decrease the motor speed on the side opposite the inflow limiting, which will decrease the patient's blood pressure and cardiac output. Normal operation will resume when the condition is resolved.

Actions

If low flow and inflow limiting occur simultaneously, the techniques for low flow management should also resolve the low flow condition.

See "How to Manage Inflow Limiting"

Contact ABIOMED for assistance if low flow occurs without inflow limiting, or if inflow limiting management techniques do not successfully resolve the low flow condition.

How to Change the Beat Rate Range Limits	
Actions	
1. Press the Menu button	Main Menu appears
2. Turn the Menu Selector Knob to select "Console Setup..."	"Console Setup..." is highlighted
3. Press the Menu Selector Knob	The Console Setup menu appears
4. Turn the Menu Selector Knob to select "Input Heart Rate Range"	"Input Heart Rate Range" is highlighted
5. Press the Menu Selector Knob	The Input Heart Rate Range popup appears
6. Rotate the Selector Knob to highlight the "Highest Allowed" box and press the knob.	The light gray selection box moves as you turn the Selector Knob. The background color of the "Highest Allowed" value turns blue when you press the knob.
7. Rotate the Selector Knob to increase or decrease the Highest Allowed Rate as clinically appropriate. Press the knob when the appropriate rate is selected.	The value changes in increments of 5 bpm as you turn the knob. The background changes back to the original color when you press the knob.
8. Rotate the Selector Knob to highlight the "Lowest Allowed" box and press the knob.	As for step 6
9. Rotate the Selector Knob to increase or decrease the Lowest Allowed Rate as clinically appropriate. Press the knob when the appropriate rate is selected.	As for step 7
10. Rotate the Selector Knob to select the "Save" button and press it.	The light gray selection box moves as you turn the Selector Knob. When you press it, the Clinical Main Screen appears.
11. Go to the Home Screen, open the Heart Rate panel, and confirm that the new limits are shown correctly.	See "How to Go to the Home Screen" and Appendix B for more detail.

How to Change To and From Automatic Motor Speed Control

Motor speed should be left in automatic control in almost all conditions except during implant surgery. The motor speed should only be put in manual control by advanced users or in consultation with ABIOMED.

Your Action	AbioCor Console Response
1. Press the Menu button	Main Menu appears
2. Turn the Menu Selector Knob to select "Show Control Buttons!"	Show Control Buttons! is highlighted
3. Press the Menu Selector Knob	Control Button labels appear
4. Press the LMS or RMS soft button.	The control button turns green and displays the current motor speed. The motor speed will change slightly with each beat.
5. To change to automatic control, turn the Selector Knob until the control button label displays "Auto". To change to manual control, turn the Selector Knob until the control button label displays the desired motor speed.	The control button label turns yellow and displays values as you turn the knob.
6. Press the Selector Knob.	The Console sends the new setting to the implanted controller. The control button label turns green and displays the current motor speed.
7. Confirm the change on the status bar motor speed display.	The motor speed should change to the new setting within 10 seconds.
8. Continue to monitor the patient's hemodynamics.	

How to Change the Home Screen to the Clinical Screen	
Your Action	**AbioCor Console Response**
1. Press the Menu button	Menu appears
2. Turn the Menu Selector knob to select "Enter Clinical Screens" on the Menu	"Enter Clinical Screens" option is highlighted
3. Press the Menu Selector Knob	Soft buttons are relabeled with letters as shown in Table 4.4
4. Press the soft buttons in sequence to spell "H-E-A-R-T" (2,2,1,6,6)	The Clinical Mode screen appears Note: if the AbioCor is in Implant Mode, the Implant Mode screen will appear

Appendix H: Federal Communications Commission (FCC) Notice

AbioCor Components	Notice
AbioCor Console	This device complies with Part 18 of the FCC Rules.
PCE Control Module	This device complies with Part 18 of the FCC Rules.
RF Communication Module	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Handheld Monitor	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Implantable Controller	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.

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AbioCor®

Implantable Replacement Heart System

PATIENT MANUAL

ABIOMED®

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AbioCor®

Handheld Monitor

INSTRUCTIONS FOR USE

ABIOMED®

Humanitarian Device. Authorized by Federal law for use in the treatment of patients with irreparably damaged hearts, at imminent risk of death with no other treatment options. The effectiveness of this device for this use has not been demonstrated.

IMPORTANT NOTICE: Read the entire *Instructions for Use* before using the Handheld Monitor. The Handheld Monitor is to be used only in accordance with the *Instructions for Use*.

Manufactured by:
ABIOMED, Inc.
22 Cherry Hill Drive
Danvers, MA 01923 USA

N. America: 1-877-ABIOCOR (224-6267) (24-Hour Emergency Hotline) or 978-777-5410

August 2004

Information contained in this document is subject to change without notice.

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About This Manual

This manual provides the *Instructions for Use* for the Handheld Monitor used by patients who have received the AbioCor® Implantable Replacement Heart System (AbioCor).

These *Instructions for Use* are intended to be used by clinicians, caregivers, and AbioCor patients.

For more information about the AbioCor System, refer to the *AbioCor Clinician Manual*; the *AbioCor Patient Manual*; the *AbioCor Patient-Carried Electronics Manual*; and the *AbioCor Console Alarms User's Guide.*

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Cautions

NOTE: A caution indicates a situation in which equipment may malfunction, be damaged, or cease to operate.

- Do ***not*** use the Handheld Monitor close to an operating AbioCor® Console. The RF signals from the AbioCor Console and the Handheld Monitor will interfere with each other and ***not allow adjustments to be made to the Implanted System***. If RF interference occurs, turn off the Handheld Monitor.

- The Handheld Monitor does ***not*** use an indicator to display the status of its battery. However, the alarm message "Handheld Battery" is displayed when the battery is low. You should charge the Handheld Monitor battery every night, whether it is used or not.

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Overview

The AbioCor® Handheld Monitor is a Personal Digital Assistant (PDA) that communicates with the AbioCor® Implanted Controller. This allows you to quickly access important information about the AbioCor System without using the AbioCor® Console. You can use the Handheld Monitor to:

- Respond to a Heart Alarm on the PCE Module.
- Check AbioCor status.
- Check AbioCor settings and alarm history.

You ***cannot*** make changes to Beat Rate, Motor Speed, or Balance settings using the Handheld Monitor. These changes must be made using the Console.

Before using the Handheld Monitor, you must be trained in the operation of both the AbioCor® PCE and the AbioCor® Console.

Components of the AbioCor® Handheld Monitor

- **RF Expansion Module** – allows the Handheld Monitor to communicate with the Implanted Controller; draws power from the Handheld Monitor's battery (even when the unit is off).
- **Handspring® Personal Digital Assistant (PDA)** – standard PDA used as the interface component of the Handheld Monitor.
- **Stylus** – used to select items on the screen (fingers can also be used).
- **Charger** – plugs into an AC outlet to charge the Handheld Monitor's battery.

RF Expansion Module

Charger

Handspring®
PDA

Stylus

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Components of the AbioCor® Handheld Monitor

Controls and Features

- **Life-Threatening Alarm Light** – flashes when a life-threatening alarm condition exists; it also flashes briefly when the RF Expansion Module is inserted.
- **Application Button** – used to access the AbioCor Settings Screens and Alarm History Screen.
- **Power Button** – turns the Handheld Monitor on and off; the screen automatically turns off (to save power) if the unit has not been used for 2 minutes.
- **Touch-Sensitive Screen** – displays information; responds to the stylus.
- **Scroll Buttons, Up/Down Arrows, and Scroll Bar** – used to move through information on the screen.

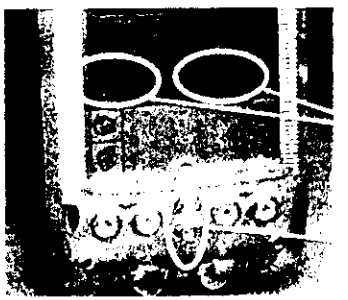
Life-Threatening Alarm Light

Application Button

Power Button

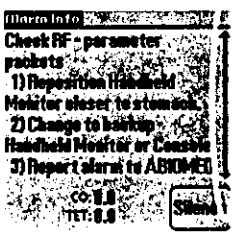
Touch-Sensitive Screen

(Not used)



Up/Down Arrows

Scroll Buttons



Scroll Bar

Resolving Alarms

1

The Handheld Monitor's AbioCor Alarms screen allows you to view two types of alarms: ***active*** and ***inactive***.

- **Active alarm** – an existing alarm that has ***not*** been acknowledged ("silenced"); indicated by a ***flashing*** alarm message.
- **Inactive alarm** – an existing alarm that has been acknowledged; becomes active again if it is not resolved within 2 minutes; indicated by a ***solid*** (not flashing) alarm message.

NOTE: Alarms that have been resolved without action or acknowledgement may be displayed as solid alarm messages.

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Alarms are divided into three levels: ***Life Threatening, Serious, and Advisory***. The following message display methods are used to distinguish each level:

- **Life Threatening** – Active: flashes between black text on light background and light text on black background. Inactive: solid light text with black background.

  NOTE: The Life-Threatening Alarm Light also flashes ***red*** for Active and Inactive.

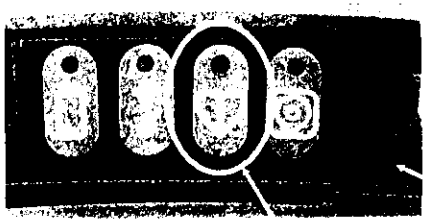
Life-Threatening Alarm Light

- **Serious** – Active: flashes between black text and textured text. Inactive: solid black text.
- **Advisory** – Active: flashes "INFO" between black text and textured text. Inactive: solid black text.

Resolving Alarms (continued)

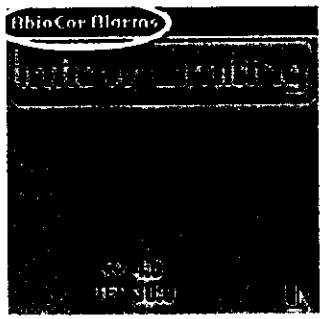
3

When the Heart Alarm (visible and audible) on the PCE Module is activated, move the Handheld Monitor close to the Implanted Controller (stomach area) and turn it on. The AbioCor Alarms screen appears.



Heart Alarm

PCE Module



AbioCor Alarms Screen

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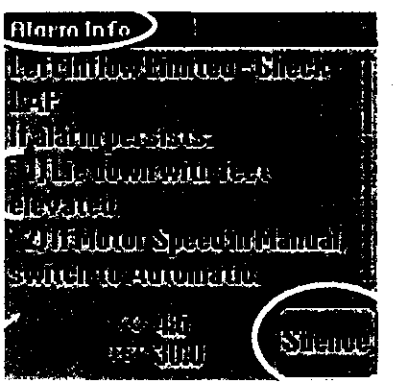
Alarms are listed in order of importance. The most important alarm is at the top of the list.

a. Using the stylus (or your finger), tap the alarm at the top of the list. The Alarm Info screen appears.

b. Follow the instructions in the ***first step only***.

c. Tap Silence to acknowledge the alarm. This returns you to the AbioCor Alarms screen. Check whether the alarm is still listed.



Alarm Info Screen

Resolving Alarms (continued)

5

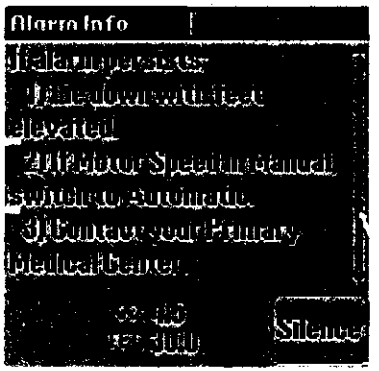
If the alarm is still listed:

a. Tap the alarm. The Alarm Info screen appears.

b. Follow the instructions in the ***next step only***.

c. Tap Silence to return to the AbioCor Alarms screen.

d. Continue in this manner, performing ***one step at a time***, until the alarm has cleared.



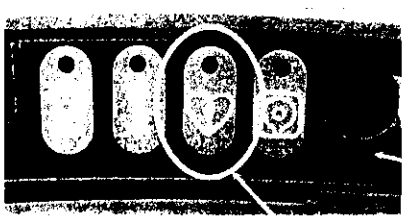
Scroll Bar

NOTE: Be sure to use the scroll bar to view additional instructions that do not fit on a single screen.

If the alarm is no longer listed, tap the alarm that is now at the top of the list. Begin again with the procedure described on the previous page.

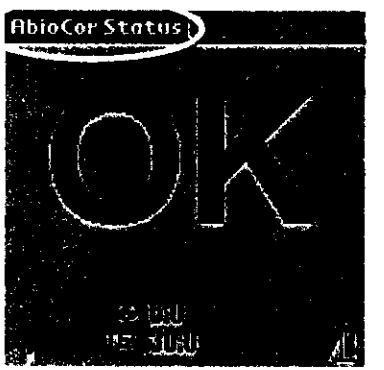
6

When all alarms are resolved, the AbioCor Status screen appears, and the Heart Alarm indicator on the PCE Module turns off.



PCE Module

Heart Alarm



AbioCor Status Screen

Checking AbioCor Status

1

Turn on the Handheld Monitor. Either the AbioCor Status screen or the AbioCor Alarms screen appears:

- If the AbioCor Status screen appears, proceed to the following page.
- If the AbioCor Alarms screen appears (displaying a "Check RF" alarm), move the Handheld Monitor closer to the Implanted Controller (stomach area). The "Check RF" alarm should clear.

CAUTION: *Do* ***not*** *use the Handheld Monitor close to an operating AbioCor® Console. The RF signals from the Console and the Handheld Monitor will interfere with each other and* ***not allow adjustments to be made to the Implanted System.*** *If RF interference occurs, turn off the Handheld Monitor.*

2

The AbioCor Status screen provides the following information:

- **CO** – indicates AbioCor blood flow in liters per minute (L/min).
- **TET** – indicates system voltage in VDC.
- **ABIOMED logo** – appears to rotate when the program is operating.

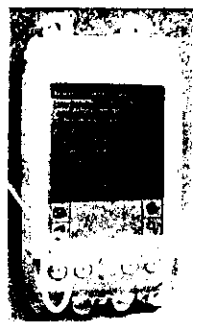
CO TET ABIOMED logo

Checking AbioCor Settings and Alarm History

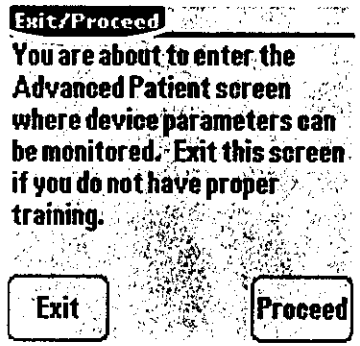
1

Press the application button ***twice***. The Exit/Proceed screen appears.

Application Button



Exit/Proceed Screen

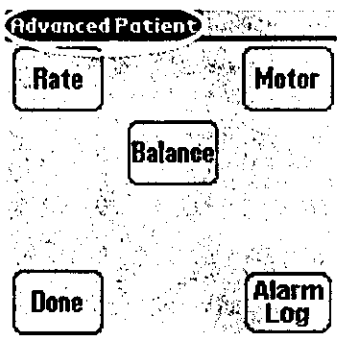


460

2

Tap Proceed on the Exit/Proceed screen. The Advanced Patient screen appears. This screen allows you to access the following information (see sample screens on the following pages):

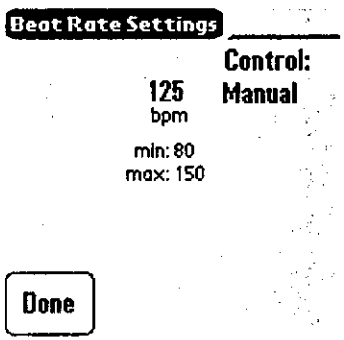
- **Beat Rate** – current, minimum, and maximum settings; control status (manual).
- **Balance** – current setting; control status (manual or automatic).
- **Motor Speed** – current settings; control status (manual or automatic).
- **Alarm History (Log)** – most recent 10 alarms.

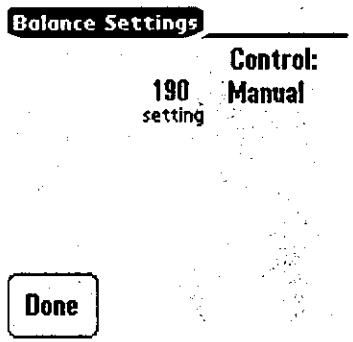


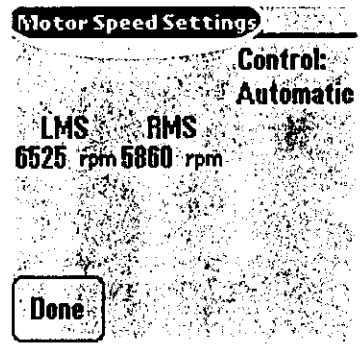
Advanced Patient Screen

Checking AbioCor Settings and Alarm History (continued)

3







NOTE: Tapping Done returns you to the AbioCor Status screen (or, if an alarm exists that has not been acknowledged, to the AbioCor Alarms screen).

462

4

This information concerns the most recent alarm. Scroll to view the details of the 10 most recent alarms.

AbioCor Alarm History Screen

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Charging the Battery

1

⚠ ***CAUTION:*** *The Handheld Monitor does* ***not*** *use an indicator to display the status of its battery. However, the alarm message "Handheld Battery" is displayed when the battery is low.*

Charge the Handheld Monitor's battery every night, whether it is used or not. When possible, you should keep the backup Handheld Monitor available while the other unit is charging. It takes about 90 minutes to charge the battery.

NOTE: The screen remains on during charging, even if the Handheld Monitor was turned off prior to charging.

2

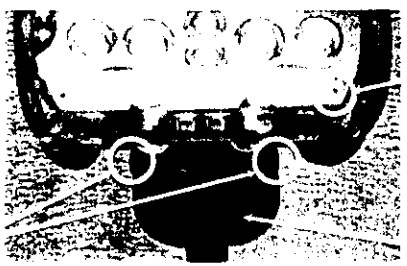
To charge the battery:

a. Plug the charger connector into the Handheld Monitor.

b. Plug the charger into an AC outlet. The charging light blinks while the battery is charging. When the light stays on, the battery is charged.

c. Unplug the charger from the outlet.

d. Squeeze the release buttons (between thumb and forefinger) and unplug the charger connector.



Troubleshooting

Symptom	Solution
The screen is frozen, **OR** **The Handheld Monitor chirps repeatedly.**	• Remove the RF Expansion Module and then reinsert it. • If the screen is still frozen, reset the Handheld Monitor by unscrewing the stylus tip and inserting the smaller end into the RESET hole on the back of the unit.  • If the problem still exists, change to the backup Handheld Monitor or AbioCor® Console.

Symptom	Solution
The Handheld Monitor does not turn on.	• Follow the procedure described in *Charging the Battery*. Turn on the Handheld Monitor. • If the problem still exists, change to the backup Handheld Monitor or AbioCor® Console.

Care and Cleaning

- Be careful not to scratch the screen. Only use the stylus or fingers when touching the screen. Do not use pens, pencils, or other sharp objects on the screen.
- The Handheld Monitor is not waterproof and should not be exposed to rain, moisture, or extremely dusty conditions.
- To prevent damage to the screen, be careful not to drop the Handheld Monitor or subject it to strong impact.
- Protect the Handheld Monitor from extreme temperature environments (such as the dashboard of a closed car during hot weather), heaters, and other heat sources.
- To clean the Handheld Monitor, use a soft, damp cloth. To clean the screen, use a soft cloth moistened with diluted window-cleaning solution.

Appendix: Federal Communications Commission (FCC) Notice

AbioCor Components	Notice
AbioCor® Console	This device complies with Part 18 of the FCC Rules.
PCE Module	This device complies with Part 18 of the FCC Rules.
RF Communication Module	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Handheld Monitor	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Implantable Controller	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.

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or
978-777-5410

AbioCor®

Implantable Replacement Heart System

Pre-Implant Equipment Check and Implant Procedures

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August 2004

Humanitarian Device. Authorized by Federal law for use in the treatment of patients with irreparably damaged hearts, at imminent risk of death with no other treatment options. The effectiveness of this device for this use has not been demonstrated.

IMPORTANT NOTICE: Read this ***entire*** manual before implanting the AbioCor Implantable Replacement Heart (AbioCor). The AbioCor is to be used only in accordance with this manual and the *AbioCor Clinician Manual.*

Information contained in this document is subject to change without notice.

Contents

List of Figures

About This Manual

This manual provides instructions for:

- Checking the performance and condition of the equipment used for implantation
- Implanting the AbioCor® Implantable Replacement Heart System

When implanting the AbioCor, use this manual in conjunction with the *AbioCor Clinician Manual.*

These instructions are not intended to substitute for the independent medical judgment of each medical professional.

Section 1
Warnings and Cautions

In This Section

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Warnings

- Only an authorized user is permitted to change AbioCor® Console alarm properties.
- Locate the Implantable TET at least ***3 inches*** from pacemakers, AbioCor System components, and any implanted metal.
- To prevent corrosion or electrical malfunction, do ***not*** allow any contaminating material, saline, blood products, O-ring lubricant, etc. to contact any electrical connectors or connector pins.
- To allow effective de-airing, make sure the side arms of the grafts are positioned at the highest points (the locations at which air bubbles would tend to lodge) when sewing the grafts.
- Position quick connector prongs so they will not damage cuffs, grafts, or tissue.
- During De-Airing and Startup, make sure LHP and/or RHP do ***not*** decrease to < – 50 mmHg. If this occurs, select **Pause** and reposition the Thoracic Unit. Check for inflow obstructions.
- Before attaching locking clips, use the gap gauge at the end of the snap ring assembly tool to confirm that the connections to the quick connectors are properly made and secure.
- Immediately after clamping the right side arm, confirm that left atrial pressure rapidly increases. If it does not, press **Pause**, increase cardiopulmonary bypass (CPB) flow, and check for inflow obstructions.
- Air embolism is possible if air is present in the left and/or right blood pumps. ***Be sure that all air has been removed from the blood pumps***.

- Do ***not*** allow any metal objects within ***3 inches*** of the External TET while it is powered. Certain types of metal objects may quickly become extremely hot and present a burn or fire hazard.
- When the TET system is powering the Thoracic Unit, before the Implantable Battery is connected, do ***not*** allow the External TET to move out of position. If the External TET moves out of position, the Thoracic Unit will ***stop pumping***. Critical system settings, ***including beat rate and balance***, will reset to ***default values*** when power is restored.
- To minimize the potential for abrasion of the PA outflow graft, wrap the graft with PTFE felt.
- To prevent air from entering the system, closely monitor the patient and the system for signs of inflow limiting.

Cautions

*A **caution** indicates a situation in which equipment may malfunction or be damaged.*

- Do ***not*** allow the Sterile O-Ring Lubricant to contact Implantable Cable connector pins or any implantable component.
- Do ***not*** place a powered External TET on a metal surface: the External TET and the metal surface will become hot and may be damaged.

Section 2
Pre-Implant Equipment Check

In This Section

490

Checkboxes ☐ are provided to confirm that steps have been performed.

Setting Up the Console

☐ **1** Inspect the Console for visible damage.

☐ **2** Turn on the Console and allow the Self-Test to run. This test includes:

- Flashing the LED indicators on the right side of the front panel
- Sounding the alarm indicator
- Testing the computer and software

☐ **3** Press MENU and select **Console Setup > Enter Standby Mode**. Select "I Confirm".

☐ **4** Test the Console backup battery:

a. Unplug the AC power cord from the power outlet.

b. Confirm that the Console Battery voltage is > 31.0 volts.

c. Plug in the AC power cord.

☐ **5** Enable all alarms:

a. Press MENU and select **Console Setup > Alarms**. The entry confirmation window appears. If applicable, select **Accept**.

b. Alarm categories with checked boxes in the Masked column need to be ***enabled***. Select a category that has a checked box. (If no categories have checked boxes, proceed to "Checking Sterile Components.")

c. Press the selector knob (button background turns yellow).

d. Press the selector knob again (button background turns white).

e. Scroll to the Alarm column and enable the alarm by pressing the selector knob.

f. Scroll back to the alarm title and press the selector knob (button background turns yellow). Then select **Accept**.

g. Repeat this procedure for any alarm category with a checked box.

h. Select **Send** to save the setting. Then select **Exit**.

Checking Sterile Components

Following the instructions on the Thoracic Unit packaging, unpack the sterile components and equipment. Perform the following:

☐ • Test fit the cuffs and grafts on the Thoracic Unit.

☐ • Inspect electrical connectors for:

- Bent or darkened electrical pins
- Damaged O-rings

☐ • Inspect for damaged gaskets on the inflow and outflow quick connectors of the Thoracic Unit.

☐ • Apply Sterile O-Ring Lubricant to all white O-rings on the electrical connectors. Use the dispensing tip (not fingers) to evenly spread the lubricant.

CAUTION: *Do **not** allow the Sterile O-Ring Lubricant to contact Implantable Cable connector pins or any implantable component.*

☐ • Record the serial numbers of the implantable components on the ***Device Tracking Form.***

Checking Signal Interface Unit Operation

Connecting Components

Steps shaded in gray are to be performed by the Console Operator.

1 Connect the clear (no color band) connector of the Implantable Cable to the Implantable Controller and tighten with the spanner wrench.

2 Connect the purple connector of the Implantable TET to the purple connector of the Implantable Cable and ***hand tighten*** only.

3 Set the Signal Interface Unit switch to the ***TET*** position. Connect the blue connector of the Implantable Cable to the Signal Interface Unit and ***hand tighten*** only.

4 Pass the Fischer® connector end of the Signal Interface Unit cable to the Console Operator.

5 Plug the Fischer connector end of the Signal Interface Unit cable into the Console "Thoracic" connector.

6 Set the Signal Interface Unit switch to the ***Console*** position.

Establishing Direct Communication with the Implantable Controller

1 Press MENU and select **AbioCor Setup > Select Controller > Controller Source > Direct Comm**.

2 Select the transmitter ID:

a. Press MENU and select **AbioCor Setup > Select Controller**. Choose **Select ID from list**.

b. Select the number at the top of the list. Record this number on the ***Device Tracking Form***.

c. Select **Accept**.

Checking the TET System

CAUTION: *Do **not** place a powered External TET on a metal surface: the External TET and the metal surface will become hot and may be damaged.*

1 Connect the External TET cable to the Console.

2 Maintain a minimum distance of 3 inches between the External TET and a metal (table) surface by placing the TET on a pile of sterile towels.

3 Move the External TET to within about 1 inch of the Implantable TET.

4 Confirm that the "Normal" indicator is displayed on the Console.

5 Set the Signal Interface Unit switch to the ***TET*** position.

6 Make sure the system voltage displayed on the Console is 28 to 32 volts.

7 Set the Signal Interface Unit switch to the ***Console*** position.

8 Move the External TET at least 1 foot away from the Implantable TET.

9 Disconnect the External TET cable from the Console. Cap and secure the nonsterile end of the cable.

Operating the Thoracic Unit

1 Press [MENU] and select **View > Enter Implant Mode!** Press the Pause soft button. Confirm that "Paused" is displayed in the motor speed (LMS RMS) field on the Console.

2 Connect the yellow connector of the Implantable Cable to the yellow connector of the Thoracic Unit and ***hand tighten*** only.

3 Carefully hold the Thoracic Unit to prevent movement that could damage the inflow and outflow connectors.

4 Press Left to toggle to the left and then Right to toggle to the right. Press Pause.

5 Choose the "30 5000 5000" Startup by pressing **Startups** and using the selector knob.

6 Allow the Thoracic Unit to run for about 3 minutes.

7 Gently occlude the inflow and outflow ports of the Thoracic Unit.

8 Confirm that the hydraulic pressure transducer signals change appropriately.

9 Set the balance control as follows and confirm that the displayed balance setting changes appropriately:

   a. 0

   b. 400

   c. 0

   d. 400 – At this setting, make sure the Balance Chamber membrane completely stops. ***Leave the balance at this setting.***

10 Press Pause.

Calibrating the Hydraulic Pressure Transducers

1 Press [MENU] and select **AbioCor Setup > Set Hydraulic Pressure Offsets**.

2 Confirm that the current offset values for left hydraulic pressure (LHP) and right hydraulic pressure (RHP) are 0.0.

3 Position the Thoracic Unit with the inflow and outflow connectors facing up.

4 Confirm that the LHP and RHP values (located to the right of the pressure waveforms on the Console) are 0 mmHg ± 70 mmHg.

5 Using the selector knob, enter an offset value for LHP that, when added to the displayed LHP value, results in a sum of zero. ***Refer to the example at left.***

6 Using the same method employed for determining LHP offset, enter an offset value for RHP.

7 Record the LHP and RHP offset values on the ***Device Tracking Form***.

8 Save the values in the Implantable Controller by selecting **Send Desired**. The displayed LHP and RHP values should now be 0 mmHg ± 2 mmHg.

9 Select **Exit**.

***Example** of determining an **offset value**: If the displayed LHP value is 10.4 mmHg, the correct offset value is – 10.4 mmHg.*

Checking RF System Operation

1 Establish RF communication with the Implantable Controller by selecting **Controller > RF comm.**

2 Set the Signal Interface Unit switch to the *TET* position.

3 Disconnect the Thoracic Unit from the Implantable Cable.

4 Disconnect the Signal Interface Unit cable from the Console. Cap and secure the nonsterile end of the cable.

5 Disconnect the Implantable Cable from the Signal Interface Unit.

6 Connect the RF Communication Module to the Console.

7 Connect the blue connector of the Implantable Cable to the Implantable Battery.

8 Press [MENU] and select **Show Control Buttons!**

9 ***To confirm RF communication*** with the Implantable Controller, set the balance control to 250. Confirm that the displayed balance setting changes to 250.

10 Confirm that the displayed "Implanted Battery" voltage is > 23.5 volts.

Preparing Components for Implant

1 Disconnect the Implantable TET and the Implantable Battery from the Implantable Cable.

2 Attach bullets to the Implantable TET, Implantable Battery, Thoracic Unit, and all open Implantable Cable ends.

3 Attach holding fixtures to cuffs and grafts.

4 Place black caps on the inflow and outflow connectors of the Thoracic Unit.

Section 3
Implant Procedures

In This Section

Implanting the TET, Controller, and Thoracic Unit

Placing the Implantable TET and the Implantable Controller

1 Perform a standard sternotomy.

2 Using blunt dissection, form a pocket for the Implantable TET on the right-hand side in subclavicular tissue (Figure 1). Place the TET in the pocket (about ½ inch deep). Tunnel the TET cable over the ribs and out through the sternotomy incision.

WARNING: *Locate the Implantable TET at least **3 inches** from pacemakers, AbioCor System components, and any implanted metal.*

3 Form pockets for the Implantable Controller and Implantable Battery below the posterior sheath of the peritoneum (Figure 1).

WARNING: *To prevent corrosion or electrical malfunction, do **not** allow any contaminating material, saline, blood products, o-ring lubricant, etc. to contact any electrical connectors or connector pins.*

4 Place the Implantable Controller in the pocket. Connect the purple connector of the Implantable TET to the purple connector of the Implantable Cable.

5 Make sure the Signal Interface Unit switch is in the ***TET*** position.

6 Connect the blue connector of the Implantable Cable to the Signal Interface Unit and ***hand tighten*** only.

DRAFT FIGURE – PLACEHOLDER USE ONLY

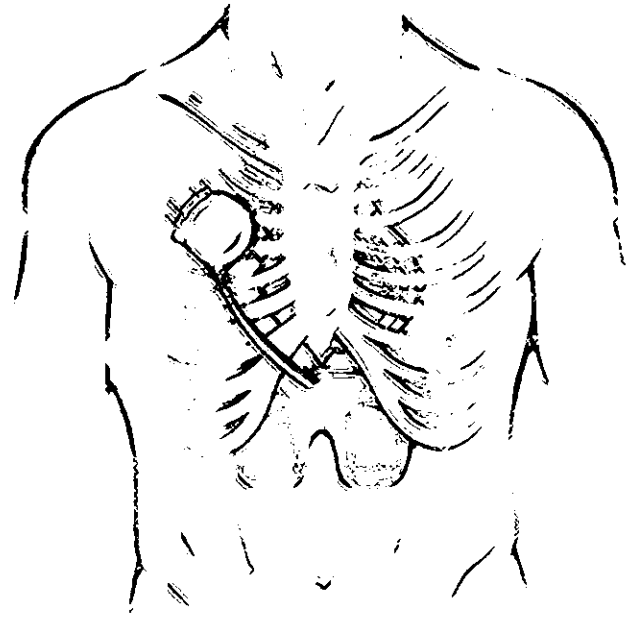

Figure 1: Forming Pockets for Implantable Components

***Steps shaded in gray** are to be performed by the **Console Operator**.*

7 Connect the patient pressure monitoring cable (if used) to the Console.

8 Pass the Fischer® connector end of the Signal Interface Unit cable to the Console Operator.

9 Plug the Fischer connector end of the Signal Interface Unit cable into the Console "Thoracic" connector.

10 Set the Signal Interface Unit switch to the ***Console*** position.

11 Establish communication with the Implantable Controller by pressing [MENU] and selecting **AbioCor Setup > Select Controller > Controller Source > Direct Comm**.

12 Press [MENU] and select **View > Enter Implant Mode!** Press the Pause soft button. Confirm that "Paused" is displayed in the motor speed (LMS RMS) field on the Console.

13 Set the balance control to 400.

Setting Valve Powers to Default Values

Press [MENU] and select **AbioCor Setup > Automatic Control Parameters > Stroke Control Parameters**. Confirm that Valve Powers are set to the following default values:

p0	p1
60	10

p2	p3
20	20

- If the Valve Powers ***are*** set to the default values, select **Exit**.
- If the Valve Powers ***are not*** set to the default values, change the values using the selector knob. Choose **Send** to save the new values. Then select **Exit**.

Removing the Ventricles

1 Open the pericardium and expose the heart and great vessels.

2 Place the patient on standard CPB.

3 Remove the ventricles (Figure 2). Cut the tissue between the atria and ventricles leaving adequate left and right atrial tissue for attaching inflow cuffs.

DRAFT FIGURE – PLACEHOLDER USE ONLY

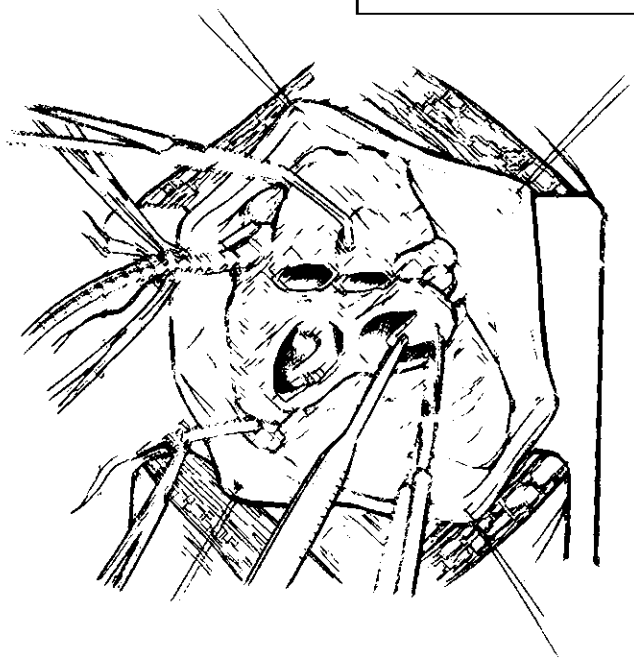

Figure 2: Removing the Ventricles

Two types of cuffs are provided: one with and one without a stent. The use of the stented cuff requires surgical attention to prevent the stent from being in persistent contact with some parts of the inner atrial wall. If a patient's atrial tissue is fragile with potential for bleeding complications, the sewing must be performed at the annulus. The limited size of the annulus precludes the use of the stented cuff because the stent would be in constant contact with atrial tissue. This contact site may cause clots to form, increasing the risk for strokes. In this case, the stentless cuff is used.

4 Cut the tissue between the ventricles and the aorta and pulmonary artery (PA) distal to their respective valves. Leave enough tissue for the inflow cuffs to be attached. Trim or oversew excess tissue on the atrial appendages to prevent possible prolapse into the inflow valves.

5 If a patent foramen ovale exists, suture it closed to prevent passage of blood between the two atria. Oversew the coronary sinus.

Attaching the Atrial Cuffs

1 Trim the ***left*** atrial cuff to the appropriate size. Then sew the cuff to the left atrial tissue and to a reinforcing layer of PTFE felt using a running polypropylene suture. Reinforce the anastomosis by sewing a second layer of felt around it.

2 Check the left atrial anastomosis for leaks:

   a. Snap the leak checker into the left atrial cuff.

   b. Inflate the Foley catheter with 60 cc of air.

   c. Pressurize the atrium with water and inspect for leaks.

3 Use a gauge to position the right atrial cuff. Anastomose the right atrial cuff to the right atrial tissue using a procedure similar to the one used for the left atrial cuff. Be sure to prevent overlapping stitches with the left atrial anastomosis.

4 Check the right atrial anastomosis for leaks using the leak checker without the Foley catheter.

Attaching the PA and Aortic Outflow Grafts

1 Attach the AbioCor fit model to the left and right atrial cuffs.

2 Determine the length and orientation of the PA outflow graft and remove the model.

WARNING: *To allow effective de-airing, make sure the side arm of the graft is positioned at the highest point (the location at which an air bubble would tend to lodge) when sewing the graft in the following step.*

3 Trim the PA outflow graft to the appropriate length and sew to the PA using a running suture and a reinforcing layer of PTFE felt.

4 Cross-clamp the PA. Check the anastomosis for leaks using the leak checker without the Foley catheter.

5 Choose one of the three types of aortic outflow grafts (various types are provided to accommodate anatomical variations and allow effective de-airing).

6 Attach the aortic outflow graft to the AbioCor fit model and place the model in the chest. Connect the left atrial, right atrial, and PA quick connectors to the model.

7 Begin rewarming the patient.

8 Determine the length and orientation of the aortic outflow graft and remove the model.

⚠ ***WARNING:*** *To allow effective de-airing, make sure the side arm of the graft is positioned at the highest point (the location at which an air bubble would tend to lodge) when sewing the graft in the following step.*

---

9 Trim the aortic outflow graft to the appropriate length and sew to the aorta using a running suture and a reinforcing layer of PTFE felt. Check the anastomosis for leaks using the leak checker without the Foley catheter.

10 Apply surgical glue to the left atrial, right atrial, aortic outflow, and PA outflow graft seams. Be sure to prevent glue from contacting ***any metal surface***.

11 Insert a Millar® pressure transducer through the right chest wall and into the left atrium via the pulmonary vein. Test for signal response on the patient monitor.

Placing the Thoracic Unit

WARNING: *To prevent corrosion or electrical malfunction, do* ***not*** *allow any contaminating material, saline, blood products, o-ring lubricant, etc. to contact any electrical connectors or connector pins.*

WARNING: *Before attaching locking clips, use the gap gauge at the end of the snap ring assembly tool to confirm that the connections to the quick connectors are properly made and secure.*

1 Fill the blood pumps with heparinized saline.

2 Place the Thoracic Unit in the pericardial space. Remove the caps (one at a time, as each connection is made) and make the following connections (Figure 3) ***in order***:

   a. Left atrial cuff – Attach the locking clip.

   b. PA outflow graft – Attach the locking clip.

   c. Aortic outflow graft – Position the quick connector prongs about 180 degrees away from the fill port of the Thoracic Unit to allow clearance for the locking clip. Attach the locking clip.

3 Position the surgical table so that the right inflow connector of the Thoracic Unit is at the highest point. Remove the inflow cap. Insert a soft rubber catheter (attached to a bulb syringe) through the right inflow valve and fill the right blood pump and the right atrium as much as possible.

4 Connect the right atrial cuff to the right inflow connector. Attach the locking clip.

5 Reposition the surgical table as necessary.

WARNING: *Position quick connector prongs so they will not damage cuffs, grafts, or tissue.*

DRAFT FIGURE – PLACEHOLDER USE ONLY

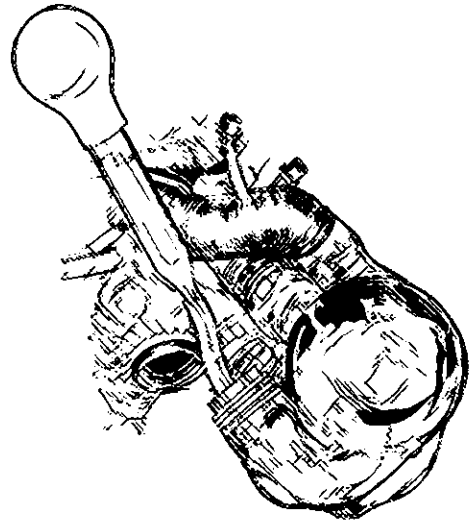

Figure 3: Connecting to the Thoracic Unit

De-Airing and Startup

De-Airing

1 Select **Console Setup > exit standby mode.**

2 Connect the yellow connector of the Implantable Cable to the yellow connector of the Thoracic Unit (Figure 4) and tighten with the spanner wrench.

DRAFT FIGURE – PLACEHOLDER USE ONLY

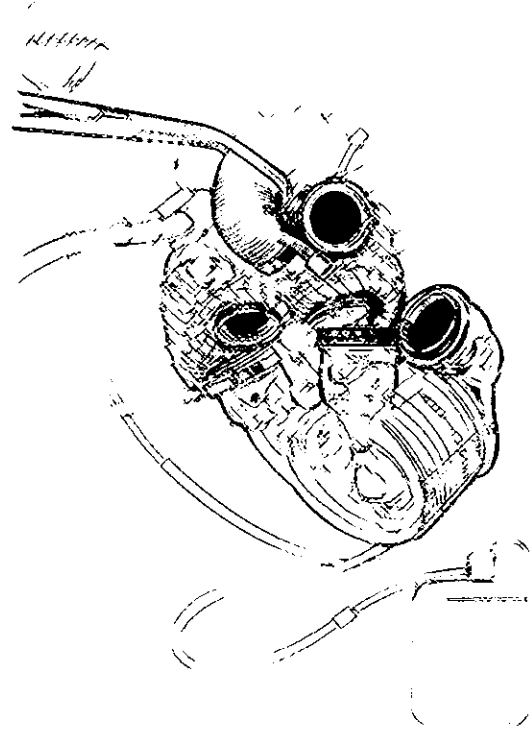

Figure 4: Connecting the Implantable Cable to the Thoracic Unit

3 Attach Toomey syringe bodies to the side arms of the outflow grafts and place suckers in the syringe bodies (Figure 5). Loosely cover with 4x4 to prevent spillage.

DRAFT FIGURE – PLACEHOLDER USE ONLY

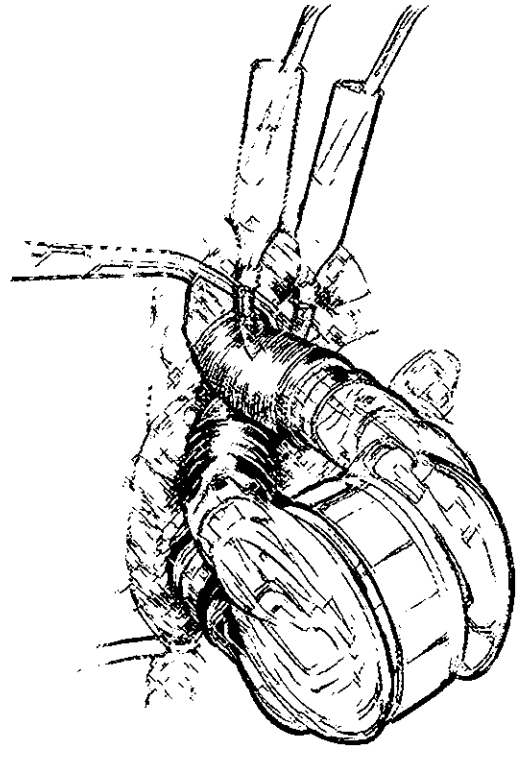

Figure 5: Attaching Toomey Syringe Bodies to Side Arms

4 Release the caval tapes and allow the right atrium to fill. Partially occlude the venous return.

5 Fill the Thoracic Unit by increasing central venous pressure (CVP) to 15 to 20 mmHg. Maintain CVP within this range during the de-airing procedure.

6 Carefully support the Thoracic Unit to prevent occluding the inflow components.

7 Resume ventilation.

WARNING: *During De-Airing and Startup, make sure LHP and/or RHP do* ***not*** *decrease to < – 50 mmHg. If this occurs, select* ***Pause*** *and reposition the Thoracic Unit. Check for inflow obstructions.*

---

8 Press the Left soft button to toggle to the left. Then press Right to toggle to the right.

9 Continue toggling as necessary to confirm flow into and out of the Thoracic Unit. Be sure that there are no leaks or obstructions to flow.

10 Press Pause.

11 Remove the superior vena cava (SVC) cannula and oversew the insertion site.

12 Begin with the low-flow Start Up states and quickly step through the first 3 states (if there are no filling problems).

13 Reduce CPB flow to 2 L/min.

14 If inflow pressure and volume are good, step through the Startup states until the right blood pump is de-aired.

WARNING: *Immediately after performing the following step, confirm that left atrial pressure rapidly increases. If it does not, press* ***Pause****, increase CPB flow, and check for inflow obstructions.*

---

15 When all air has been removed from the right blood pump, clamp the right side arm (Figure 6).

16 Place both CPB suckers into the left outflow Toomey syringe body. If necessary, increase flow (using Startup states) and adjust the position of the Thoracic Unit and the patient.

17 Use transesophageal echocardiography (TEE) to confirm that the right blood pump is de-aired.

DRAFT FIGURE – PLACEHOLDER USE ONLY

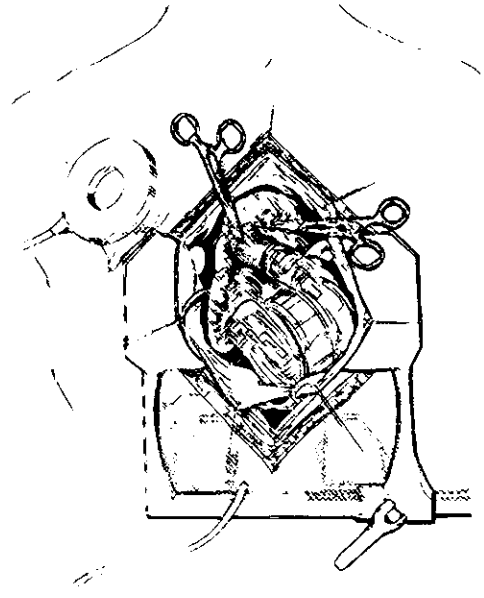

Figure 6: Clamping the Right Side Arm

18 Inspect the left blood pump and valves for air. After satisfactory inspection, allow an additional 4 to 5 minutes to ensure that the left blood pump is de-aired. Confirm this using TEE.

Transitioning from CPB

WARNING: *Air embolism is possible if air is present in the left and/or right blood pumps.* ***Be sure that all air has been removed from the blood pumps.***

1 Reduce the beat rate to 60 bpm.

2 Reduce CPB flow.

3 Simultaneously clamp the left side arm (Figure 7) and open the cross clamp. Do not allow the side arm and the cross clamp to be closed at the same time.

4 Increase Thoracic Unit flow to match physiologic conditions.

DRAFT FIGURE – PLACEHOLDER USE ONLY

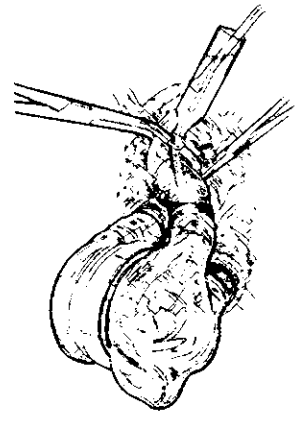

Figure 7: Clamping the Left Side Arm

The Thoracic Unit can be fastened anteriorly to the rib cage using one or more wire ligatures. This may help prevent inflow obstructions.

5 Discontinue CPB and reverse heparin.

6 Closely monitor inflow pressures and compensate by making changes to volume and Thoracic Unit settings.

7 When LHP and RHP are stable and flow is > 3 L/min, switch the Full Stroke Control to "Auto".

WARNING: *Do **not** allow any metal objects within **3 inches** of the External TET while it is powered. Certain types of metal objects may quickly become extremely hot and present a burn or fire hazard.*

CAUTION: *Do **not** place a powered External TET on a metal surface: the External TET and the metal surface will become hot and may be damaged.*

Switching to TET Power

1 Connect the External TET cable to the Console.

2 Place the External TET in the holder. Align the TET with the Implantable TET.

3 Confirm that the "Normal" indicator is displayed on the Console.

4 Sew the External TET holder in place.

WARNING: *Do **not** remove the Signal Interface Unit if the TET system is not in place and operational.*

WARNING: *When the TET system is powering the Thoracic Unit, before the Implantable Battery is connected, do not allow the External TET to move out of position. If the External TET moves out of position, the Thoracic Unit will* ***stop pumping****. Critical system settings,* ***including beat rate and balance****, will reset to* ***default values*** *when power is restored.*

5 Make sure the External TET is securely fastened. Set the Signal Interface Unit switch to the ***TET*** position.

6 Make sure the system voltage displayed on the Console is 28 to 32 volts.

7 Connect the RF box to the Console. Press MENU and select **AbioCor Setup > Select Controller > Controller Source: RF Comm** to configure the Console to receive signals from the RF box. Place the RF box in a sterile bag and pass it into the sterile field.

8 Make sure the system voltage displayed on the Console is 28 to 32 volts.

9 Disconnect the blue connector of the Implantable Cable from the Signal Interface Unit.

10 Disconnect the Signal Interface Unit cable from the Console. Cap and secure the nonsterile end of the cable.

Placing the Implantable Battery

1 Connect the blue connector of the Implantable Cable to the Implantable Battery and tighten with the spanner wrench.

2 Note (write down if necessary) the "Implanted Battery" voltage displayed on the Console.

3 Disconnect the External TET from the Console. Allow the "Implanted Battery" voltage to decrease by 0.2 volts. Then reconnect the External TET to the Console.

4 Make sure the "Implanted Battery" voltage returns to the same voltage level noted in step 2 above.

5 Press [MENU] and select **AbioCor Setup > Automatic Control Parameters > Stroke Control Parameters**. Reconfirm that Valve Powers are set to the following default values:

p0	p1
60	10

p2	p3
20	20

- If the Valve Powers ***are*** set to the default values, select **Exit**.
- If the Valve Powers ***are not*** set to the default values, change the values using the selector knob. Choose **Send** to save the new values. Then select **Exit**.

6 Place the Implantable Battery in the pocket.

Surgical Closure

1 Swab all pockets for culture.

WARNING: *To minimize the potential for abrasion of the PA outflow graft, wrap the graft with PTFE felt.*

2 Perform preclosure antibiotic wash.

WARNING: *To prevent air from entering the system, closely monitor the patient and the system for signs of inflow limiting.*

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The ***baseline fit assessment*** of the AbioCor is essential to ensure the device can perform according to specifications. A major cause of performance problems is limited blood flow to the right or left ventricle. Every effort should be made to ensure there are no fit complications. The following ***recommendations*** are intended to help minimize this problem:

3 After the AbioCor is providing full support to the patient (and hemodynamics are stable with the chest open), baseline data should be collected. These data take into account patient variables, such as atrial size, pulmonary resistance, systemic resistance, and anatomical issues:

   a. TEE should be recorded, showing lack of pressure gradients between the pulmonary veins and the left atrium.

   b. Hemodynamic parameters should be recorded, evaluating device output, central venous pressure, left atrial pressure, and aortic pressure. If possible, these numbers should be recorded at various central venous pressure levels to allow graphing of the device output response.

4 After the baseline fit assessment is complete, the chest should be approximated in the closed position. TEE and hemodynamic parameters should be reassessed, and a target velocity of < 80 cm/second should be maintained.

Other information collected prior to surgery, such as CT scans and AbioFit data, may be as review in the operating room. If changes occur, strategies to minimize fit complications should be considered. Some possibilities may include:

- Leaving the chest open until edema and bleeding is reduced
- Anchoring the device in a specific position that minimizes the fit issue

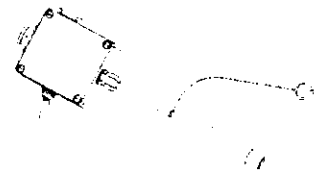
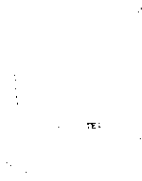
Removing ribs or part of the sternum are more radical procedures that should be avoided if possible. Chest dynamics may change due to:

- Patient position (including waking up)
- Ventilator settings (especially end expiratory pressures)
- Blood loss

Appendix A
Component Identification Guide

Low-Position Graft		
Mid-Position Graft		
High-Position Graft		

45 Degree Cuff with Stent		[Figure to be supplied]
45 Degree Cuff Assembly		
Thoracic Unit Inflow Fit Model		

Signal Interface		
Primary TET Fastener		
TET Pouch		

Leak Checker		[Figure to be supplied]
Snap Ring Assembly Tool		
Snap Ring Removal Tool		

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30-Pin Unmating Connector Tool		
Spanner Wrench		

Appendix B
Federal Communications Commission (FCC) Notice

AbioCor Components	Notice
AbioCor Console	This device complies with Part 18 of the FCC Rules.
PCE Control Module	This device complies with Part 18 of the FCC Rules.
RF Communication Module	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Handheld Monitor	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.
Implantable Controller	This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by ABIOMED Inc. could void the user's authority to operate the device.

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AbioCor®

Console Alarms

USER'S GUIDE

ABIOMED®

Humanitarian Device. Authorized by Federal law for use in the treatment of patients with irreparably damaged hearts, at imminent risk of death with no other treatment options. The effectiveness of this device for this use has not been demonstrated.

For assistance contact:

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August 2004

About This Guide

This User's Guide provides information about the alarms annunciated by the AbioCor® Console. It lists the text of alarm messages (in alphabetical order) displayed on the Clinical Screen, possible causes of alarms, and recommended actions.

This guide is designed to be used by physicians, perfusionists, critical care nurses, operating room nurses, and surgery personnel who are responsible for the care of AbioCor patients.

Organization of Alarm Information (Sample Table)

Text of the alarm message displayed on the Clinical Screen.

Possible causes are listed in the order of probability. Where possible, the most likely cause is listed first.

Information about special conditions and limitations that accompany the alarm.

RED ALARM — Category: Life-threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Implanted Battery Critically Low Implanted Battery voltage is critically low.	• External TET not aligned correctly. • External TET not working. • Extensive use of the Implanted Battery.	1. Reposition External TET. 2. Change to backup Console or PCE.	Beat rate is reduced when on Implanted Battery. Patient must use ***External TET*** until Implanted Battery voltage is greater than 22 volts.

Description of the alarm condition (if applicable).

Perform the recommended actions in sequence until the problem is resolved.

RED ALARM Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Console Battery Low: Plug into AC	• Console unplugged from AC outlet. • AC power cord unplugged from Console. • AC outlet not working. • Console failure.	1. Plug Console into working AC outlet. 2. Check that power cord is plugged into back of Console. 3. Change to backup Console or PCE.	

RED ALARM — Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Implanted Battery Critically Low Implanted Battery voltage is critically low.	• External TET not aligned correctly. • External TET not working. • Extensive use of the Implanted Battery.	1. Reposition External TET. 2. Change to backup Console or PCE.	Beat rate is reduced when on Implanted Battery. Patient must use ***External TET*** until Implanted Battery voltage is greater than 22 volts.

RED ALARM Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Low Flow Estimated Cardiac Output (CO) has decreased to less than 3 L/min.	• Left or right inflow limiting. • Low stroke volume. • High afterload. • Low beat rate.	If *left or right inflow limiting*, assess patient's fluid needs and increase patient fluid volume if needed. Assess Balance. If *low stroke volume*, check stroke volume control (look for end-of-stroke flags, check that automatic stroke volume control is enabled). If *high afterload*, consider vasodilator therapy, reposition patient. If *low beat rate*, assess beat rate.	Automatic controls are disabled. This alarm will probably occur with other alarms.

RED ALARM — Category: Life-Threatening			
Alarm Title	**Possible Causes**	**Actions**	**Notes**
Low Flow: Heart Pressure Low Low flow condition resulting from both left and right inflow limiting.	• Hypovolemia. • LA tamponade: – Patient position. – Bleeding. • High intrathoracic pressure: coughing, PEEP, high peak inspiratory pressures.	1. Reposition patient. 2. Decrease beat rate. 3. Assess volume status. Consider fluid volume replacement or vasoconstrictor therapy. 4. Consider increasing Balance setting. 5. Assess for tamponade.	Automatic controls, if enabled, will decrease right Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

RED ALARM — Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Low Flow: Increase Valve Powers Thoracic Unit may have skipped beats.	• Inaccurate Pressure Transducer readings. • Thoracic Unit's hydraulic valve sticking.	If patient is *conscious*, check Pressure Transducer offsets and correct if necessary. If patient is *unconscious:* 1. Shake patient from side to side. 2. Decrease Left Motor Speed to 4000 rpm. Decrease Right Motor Speed to 3000 rpm. 3. Restart automatic Motor Speed when problem resolves. 4. Contact ABIOMED representative and report alarm message.	Automatic unstick algorithm activated for hydraulic valve. Automatic controls are disabled.

RED ALARM — Category: Life Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Low Flow: Left Heart Pressure Low Low flow condition resulting from left inflow limiting.	• Hypovolemia. • LA tamponade: – Patient position. – Bleeding. • High intrathoracic pressure: coughing, PEEP, high peak inspiratory pressures.	1. Reposition patient. 2. Assess volume status. Consider fluid volume replacement or vasoconstrictor therapy. 3. Consider increasing Balance setting. 4. Decrease beat rate. 5. Assess ventilator status. 6. Assess for tamponade.	Automatic controls, if enabled, will decrease right Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

RED ALARM **Category: Life-Threatening**

Alarm Message and Description	Possible Causes	Actions	Notes
Low Flow: Right Heart Pressure Low Low flow condition resulting from right inflow limiting.	• Hypovolemia. • RA tamponade: – Bleeding. – High ventilator pressure. – Coughing. – Straining. • Patient position.	1. Decrease beat rate. 2. Consider fluid volume replacement or vasoconstrictor therapy. 3. Reposition patient.	Automatic controls, if enabled, will decrease left Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

RED ALARM	Category: Life-threatening		
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
TET Fault Implanted TET voltage is too high (greater than 45 volts).	• Malfunction of External or Implanted TET.	1. Increase space between External TET and patient. 2. Change to backup Console or PCE.	

YELLOW ALARMS Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Check RF Telemetry Communication with Implantable Controller has been lost.	• Poor positioning of RF Communications Box. • Interference from other RF sources. • Malfunction of RF Communications Box.	1. Realign RF Communications Box. 2. Change to backup RF Communications Box.	

YELLOW ALARM	Category: Serious		
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Check TET Alignment Implantable TET voltage is too low (less than 28 volts).	• External TET is not aligned with Implanted TET. • Malfunction of External or Implanted TET.	1. Reposition External TET. 2. Change to backup External TET. 3. Change to backup Console or PCE.	If voltage is less than or equal to 25 volts, Beat Rate reduces to 110 beats per minute.

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YELLOW ALARMS Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Check TET Connection Console cannot detect whether External TET is plugged in.	• External TET unplugged from Console. • TET cable connector failure. • Console failure.	1. Reconnect TET. 2. Change to backup TET. 3. Change to backup Console or PCE.	Beat Rate will reduce to 110 beats per minute when system is powered by Implanted Battery.
Console Battery Low: Monitor Closely	• Console not being powered by AC power. • Console failure.	Monitor battery capacity closely.	

YELLOW ALARM Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Heart Alarm Alarm condition exists in the Implanted System.	• Alarm condition in one or more of the following: – Thoracic Unit. – Implanted Controller. – Implanted Battery.	1. Establish RF communication with the Console. 2. Follow the instructions on the Console screen.	
Implanted Battery Low: Reapply TET	• Extensive use of Implanted Battery. • TET not aligned. • Malfunction of External or Internal TET.	1. Maintain RF communication. 2. Make sure External TET is available to reapply.	Beat Rate is reduced to 110 beats per minute.

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YELLOW ALARM Category: Serious			
Alarm Title	**Possible Causes**	**Actions**	**Notes**
Inflow Limited: Check LAP and RAP Left and right inflow limiting.	• Hypovolemia. • LA tamponade: – Patient position. – Bleeding. • High intrathoracic pressure: coughing, PEEP, high peak inspiratory pressures.	1. Reposition patient. 2. Decrease beat rate. 3. Assess volume status. Consider fluid volume replacement or vasoconstrictor therapy. 4. Consider increasing Balance setting. 5. Assess for tamponade.	Automatic controls, if enabled, will decrease right Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

YELLOW ALARM	Category: Serious		
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Left Inflow Limited: Check LAP	• Hypovolemia. • LA tamponade: – Patient position. – Bleeding. – High intrathoracic pressure: coughing, PEEP, high peak inspiratory pressures.	1. Reposition patient. 2. Assess volume status. Consider fluid volume replacement or vasoconstrictor therapy. 3. Consider increasing Balance setting. 4. Decrease beat rate. 5. Assess ventilatory status. 6. Assess for tamponade.	Automatic controls, if enabled, will decrease Right Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

YELLOW ALARM Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Right Inflow Limited: Check RAP Right atrial pressure possibly low.	Low RAP caused by: • Hypovolemia. • RA tamponade: – Bleeding. – High ventilator pressure. – Coughing. – Straining. – Patient position.	1. Decrease beat rate. 2. Consider providing fluid volume or vasoconstrictor therapy. 3. Reposition patient.	Automatic controls, if enabled, will decrease Left Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

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WHITE ALARM Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
AC Power Disconnected	• Console not being powered by AC power. • Console failure.	*If intentionally disconnected from AC outlet,* monitor for low battery condition. *If unintentionally disconnected:* 1. Plug Console into working AC outlet. 2. Check that power cord is plugged into back of Console. 3. Change to backup Console or PCE.	
AC Power Switch is OFF	• Console power switch is in the OFF position.	Press the Console power switch to the ON position.	

WHITE ALARM Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Console Battery Fault: Plug into AC	• Console Battery failure.	1. Make sure Console is plugged into AC outlet. 2. Change to backup Console or PCE.	Console charging system is disabled.

WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
File export failed: Check LAN setup Console cannot connect with local area network.	• Console may be disconnected from network. • Network configuration not correct.	1. Check that Console is plugged into hospital network. 2. Contact hospital information system administrators for troubleshooting.	

WHITE ALARM	Category: Advisory		
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Imp Battery Fault: Do Not Remove TET Implanted Battery is not functioning normally.	• Implanted Battery failure.	***Patient must use External TET.*** Reapply and align the TET if necessary.	If Implanted Battery has failed, removing the External TET may cause the AbioCor to ***stop pumping***.

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WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Imp Battery Overcharge Implanted Battery charging current is too high.	• Charging circuit failure.	1. ***Patient must use External TET.*** Reapply and align the TET if necessary. 2. Contact ABIOMED representative and report alarm message.	If Implanted Battery has failed, removing the External TET may cause the AbioCor to ***stop pumping***.

WHITE ALARMS	Category: Advisory		
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Implanted Battery Fault Implanted Battery temperature is too high.	• Implanted Battery temperature exceeds 55 °C. • Battery communications error.	1. Contact ABIOMED representative and report alarm message. 2. Avoid use of Implanted Battery.	

WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Left and Right Sensor Fault	• Left or right pressure transducer failure.	Operate system in Manual Mode: 1. Set Motor Speeds to last known "reliable" values. 2. Set Occluder position to last known "reliable" value.	Automatic controls are disabled. "Reliable" values are those recorded at the last stable operation.

WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Left Sensor Fault	• Left pressure transducer failure.	Operate system in Manual Mode: 1. Set Motor Speeds to last known "reliable" values. 2. Set Occluder position to last known "reliable" value.	Automatic controls are disabled. "Reliable" values are those recorded at the last stable operation.
Right Sensor Fault	• Right pressure transducer failure.	Operate system in Manual Mode: 1. Set Motor Speeds to last known "reliable" values. 2. Set Occluder position to last known "reliable" value.	Automatic controls are disabled. "Reliable" values are those recorded at the last stable operation.

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RED ALARM — Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Implanted Battery Critically Low Implanted Battery voltage is critically low.	• External TET not aligned correctly. • External TET not working. • Extensive use of the Implanted Battery.	1. Reposition External TET. 2. Change to backup Console or PCE.	Beat rate is reduced when on Implanted Battery. Patient must use ***External TET*** until Implanted Battery voltage is greater than 22 volts.

Description of the alarm condition (if applicable).

Perform the recommended actions in sequence until the problem is resolved.

RED ALARM: Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Console Battery **Low: Plug into AC**	• Console unplugged from AC outlet. • AC power cord unplugged from Console. • AC outlet not working. • Console failure.	1. Plug Console into working AC outlet. 2. Check that power cord is plugged into back of Console. 3. Change to backup Console or PCE.	

RED ALARM — Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Implanted Battery Critically Low Implanted Battery voltage is critically low.	• External TET not aligned correctly. • External TET not working. • Extensive use of the Implanted Battery.	1. Reposition External TET. 2. Change to backup Console or PCE.	Beat rate is reduced when on Implanted Battery. Patient must use ***External TET*** until Implanted Battery voltage is greater than 22 volts.

RED ALARM — Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Low Flow Estimated Cardiac Output (CO) has decreased to less than 3 L/min.	• Left or right inflow limiting. • Low stroke volume. • High afterload. • Low beat rate.	If *left or right inflow limiting*, assess patient's fluid needs and increase patient fluid volume if needed. Assess Balance. If *low stroke volume*, check stroke volume control (look for end-of-stroke flags, check that automatic stroke volume control is enabled). If *high afterload*, consider vasodilator therapy, reposition patient. If *low beat rate*, assess beat rate.	Automatic controls are disabled. This alarm will probably occur with other alarms.

RED ALARM — Category: Life-Threatening			
Alarm Title	**Possible Causes**	**Actions**	**Notes**
Low Flow: Heart Pressure Low Low flow condition resulting from both left and right inflow limiting.	• Hypovolemia. • LA tamponade: – Patient position. – Bleeding. • High intrathoracic pressure: coughing, PEEP, high peak inspiratory pressures.	1. Reposition patient. 2. Decrease beat rate. 3. Assess volume status. Consider fluid volume replacement or vasoconstrictor therapy. 4. Consider increasing Balance setting. 5. Assess for tamponade.	Automatic controls, if enabled, will decrease right Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

RED ALARM — Category: Life-threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Low Flow: Increase Valve Powers Thoracic Unit may have skipped beats.	• Inaccurate Pressure Transducer readings. • Thoracic Unit's hydraulic valve sticking.	If patient is *conscious*, check Pressure Transducer offsets and correct if necessary. If patient is *unconscious:* 1. Shake patient from side to side. 2. Decrease Left Motor Speed to 4000 rpm. Decrease Right Motor Speed to 3000 rpm. 3. Restart automatic Motor Speed when problem resolves. 4. Contact ABIOMED representative and report alarm message.	Automatic unstick algorithm activated for hydraulic valve. Automatic controls are disabled.

RED ALARM — Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Low Flow: Left Heart Pressure Low Low flow condition resulting from left inflow limiting.	• Hypovolemia. • LA tamponade: – Patient position. – Bleeding. • High intrathoracic pressure: coughing, PEEP, high peak inspiratory pressures.	1. Reposition patient. 2. Assess volume status. Consider fluid volume replacement or vasoconstrictor therapy. 3. Consider increasing Balance setting. 4. Decrease beat rate. 5. Assess ventilator status. 6. Assess for tamponade.	Automatic controls, if enabled, will decrease right Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

RED ALARM Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Low Flow: Right Heart Pressure Low Low flow condition resulting from right inflow limiting.	• Hypovolemia. • RA tamponade: – Bleeding. – High ventilator pressure. – Coughing. – Straining. • Patient position.	1. Decrease beat rate. 2. Consider fluid volume replacement or vasoconstrictor therapy. 3. Reposition patient.	Automatic controls, if enabled, will decrease left Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

RED ALARM — Category: Life-Threatening			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
TET Fault Implanted TET voltage is too high (greater than 45 volts).	• Malfunction of External or Implanted TET.	1. Increase space between External TET and patient. 2. Change to backup Console or PCE.	

YELLOW ALARMS Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Check RF Telemetry Communication with Implantable Controller has been lost.	• Poor positioning of RF Communications Box. • Interference from other RF sources. • Malfunction of RF Communications Box.	1. Realign RF Communications Box. 2. Change to backup RF Communications Box.	

YELLOW ALARM Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Check TET Alignment Implantable TET voltage is too low (less than 28 volts).	• External TET is not aligned with Implanted TET. • Malfunction of External or Implanted TET.	1. Reposition External TET. 2. Change to backup External TET. 3. Change to backup Console or PCE.	If voltage is less than or equal to 25 volts, Beat Rate reduces to 110 beats per minute.

YELLOW ALARMS Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Check TET Connection Console cannot detect whether External TET is plugged in.	• External TET unplugged from Console. • TET cable connector failure. • Console failure.	1. Reconnect TET. 2. Change to backup TET. 3. Change to backup Console or PCE.	Beat Rate will reduce to 110 beats per minute when system is powered by Implanted Battery.
Console Battery Low: Monitor Closely	• Console not being powered by AC power. • Console failure.	Monitor battery capacity closely.	

YELLOW ALARM Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Heart Alarm Alarm condition exists in the Implanted System.	• Alarm condition in one or more of the following: – Thoracic Unit. – Implanted Controller. – Implanted Battery.	1. Establish RF communication with the Console. 2. Follow the instructions on the Console screen.	
Implanted Battery Low: Reapply TET	• Extensive use of Implanted Battery. • TET not aligned. • Malfunction of External or Internal TET.	1. Maintain RF communication. 2. Make sure External TET is available to reapply.	Beat Rate is reduced to 110 beats per minute.

YELLOW ALARM Category: Serious			
Alarm Title	**Possible Causes**	**Actions**	**Notes**
Inflow Limited: Check LAP and RAP Left and right inflow limiting.	• Hypovolemia. • LA tamponade: – Patient position. – Bleeding. • High intrathoracic pressure: coughing, PEEP, high peak inspiratory pressures.	1. Reposition patient. 2. Decrease beat rate. 3. Assess volume status. Consider fluid volume replacement or vasoconstrictor therapy. 4. Consider increasing Balance setting. 5. Assess for tamponade.	Automatic controls, if enabled, will decrease right Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

YELLOW ALARM	Category: Serious		
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Left Inflow Limited: Check LAP	• Hypovolemia. • LA tamponade: – Patient position. – Bleeding. – High intrathoracic pressure: coughing, PEEP, high peak inspiratory pressures.	1. Reposition patient. 2. Assess volume status. Consider fluid volume replacement or vasoconstrictor therapy. 3. Consider increasing Balance setting. 4. Decrease beat rate. 5. Assess ventilatory status. 6. Assess for tamponade.	Automatic controls, if enabled, will decrease Right Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

YELLOW ALARM Category: Serious			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Right Inflow Limited: Check RAP Right atrial pressure possibly low.	Low RAP caused by: • Hypovolemia. • RA tamponade: – Bleeding. – High ventilator pressure. – Coughing. – Straining. – Patient position.	1. Decrease beat rate. 2. Consider providing fluid volume or vasoconstrictor therapy. 3. Reposition patient.	Automatic controls, if enabled, will decrease Left Motor Speed. If condition results in low flow, automatic controls may be ***temporarily*** turned off.

WHITE ALARM Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
AC Power Disconnected	• Console not being powered by AC power. • Console failure.	*If intentionally disconnected from AC outlet,* monitor for low battery condition. *If unintentionally disconnected:* 1. Plug Console into working AC outlet. 2. Check that power cord is plugged into back of Console. 3. Change to backup Console or PCE.	
AC Power Switch is OFF	• Console power switch is in the OFF position.	Press the Console power switch to the ON position.	

WHITE ALARM Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Console Battery Fault: Plug into AC	• Console Battery failure.	1. Make sure Console is plugged into AC outlet. 2. Change to backup Console or PCE.	Console charging system is disabled.

WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
File export failed: Check LAN setup Console cannot connect with local area network.	• Console may be disconnected from network. • Network configuration not correct.	1. Check that Console is plugged into hospital network. 2. Contact hospital information system administrators for troubleshooting.	

WHITE ALARM Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Imp Battery Fault: Do Not Remove TET Implanted Battery is not functioning normally.	• Implanted Battery failure.	***Patient must use External TET.*** Reapply and align the TET if necessary.	If Implanted Battery has failed, removing the External TET may cause the AbioCor to ***stop pumping***.

WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Imp Battery Overcharge Implanted Battery charging current is too high.	• Charging circuit failure.	1. ***Patient must use External TET.*** Reapply and align the TET if necessary. 2. Contact ABIOMED representative and report alarm message.	If Implanted Battery has failed, removing the External TET may cause the AbioCor to ***stop pumping***.

WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Implanted Battery Fault Implanted Battery temperature is too high.	• Implanted Battery temperature exceeds 55 °C. • Battery communications error.	1. Contact ABIOMED representative and report alarm message. 2. Avoid use of Implanted Battery.	

WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Left and Right Sensor Fault	• Left or right pressure transducer failure.	Operate system in Manual Mode: 1. Set Motor Speeds to last known "reliable" values. 2. Set Occluder position to last known "reliable" value.	Automatic controls are disabled. "Reliable" values are those recorded at the last stable operation.

WHITE ALARMS Category: Advisory			
Alarm Message and Description	**Possible Causes**	**Actions**	**Notes**
Left Sensor Fault	• Left pressure transducer failure.	Operate system in Manual Mode: 1. Set Motor Speeds to last known "reliable" values. 2. Set Occluder position to last known "reliable" value.	Automatic controls are disabled. "Reliable" values are those recorded at the last stable operation.
Right Sensor Fault	• Right pressure transducer failure.	Operate system in Manual Mode: 1. Set Motor Speeds to last known "reliable" values. 2. Set Occluder position to last known "reliable" value.	Automatic controls are disabled. "Reliable" values are those recorded at the last stable operation.

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